Access to Medicine Index: Can a global scorecard framework promote a system of public accountability across the pharmaceutical sector to support increased access to essential medicines in developing countries?

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a. Executive Summary

The pharmaceutical industry has since inception in the late 19th century contributed a range of health interventions that have improved and extended the quality of life of people around the world. Despite international recognition of the legal and moral right to health, one third of the global population today still lacks access to essential medicines, with a concentration in developing countries.[1] Improving access to essential medicines could save 10 million lives each year.[2] Essential medicines include medicines that satisfy the priority health care needs of a particular population based on considerations of disease prevalence, efficiency, safety and cost-effectiveness.[3]

The Access to Medicine Index (ATMi) represents a recently developed mechanism designed to evaluate the performance of the pharmaceutical sector in terms of promoting access to essential medicines. In 2012, the third ATMi was published by the Access to Medicine Foundation (ATMf). The ATMi represents the most holistic attempt to date to benchmark the performance of the global pharmaceutical sector in terms of access to essential medicines. Important distinguishing features of the index include an objective and independent body to mediate between different stakeholders, a transparent evaluation framework and access to sensitive pharmaceutical company information not otherwise publicly accessible.

The ATMi has contributed to positive changes in the pharmaceutical sector, particularly in relation to internal governance. The ATMi may also have contributed indirect value to the pharmaceutical industry by mitigating pressure and adverse publicity from civil society, to the extent that it has convincingly captured their social responsibilities and activities in improving access to medicines. However, the future effectiveness of the index in promoting substantive change across the pharmaceutical sector will be dependent on its ability to meaningfully engage and empower diverse stakeholders. Key stakeholders include governmental/intergovernmental agencies, investors, pharmaceutical sector, health care professionals, public, procurement groups, and civil society. Pharmaceutical companies will only continue to improve if the benefits are perceived to be greater than the costs of

[1] (H. Hogerzeil & Mirza, 2011 p.5)

[2] (Hunt, 2009 p.4)

[3] (WHO, 2012a, p. 16)

responding to the ATMi information needs and adapting practices. Currently, only pharmaceutical companies that perform well on the ATMi are publicly acknowledging the index results, a potential reflection of its perceived value. The ATMi needs to resonate with and unite diverse stakeholders in order for the perceived benefits to outweigh the costs of continuous improvement by the pharmaceutical sector.

This report notes a number of opportunities for the ATMi to improve its engagement with stakeholders. The current level of engagement between the ATMf and stakeholders, at least on a public level, is not strong. Consistent with the values the ATMi desires to encourage across the pharmaceutical sector, it must also espouse greater levels of objectivity, accountability, transparency and collaboration in order to further contribute to addressing the challenge of access to essential medicines.

Simplifying the measurement framework would enhance stakeholder understanding: Specifying higher standards with clearer signals of best practice and a greater focus on outcomes would further differentiate performance and reduce the number of indicators required. Examples include compliance with leading standards such as the International Standards for Clinical Trial Registries and WHO Guidelines for Good Clinical Practice, and requiring greater levels of public disclosure. Greater standardization of ATMi indicators across strategic pillars would more effectively align measures and simplify the analysis of company strengths and weaknesses. More specific and verifiable measures would also improve the ability of stakeholders to understand and trust the ATMi evaluation framework.

Strengthening the measurement framework in terms of measures, weighting and focus would enhance accuracy and completeness of findings: The ATMi should incorporate additional measures to more completely and accurately capture the performance of pharmaceutical companies concerning greater disclosure, governance, and ethical practices. Additional measures include greater disclosure of donation tax benefits and joint public private initiative governance transparency and conditions, higher ethical practices in terms of transparent product labeling and distribution traceability, and greater leading access practices in terms of expanding research into pediatric formulations and the Trans-Pacific Partnership Agreement. Greater consistency in disease and medicine focus would ensure limited resources of ATMi are most effectively targeted. Currently, the ATMi includes in its disease

scope tetanus and measles for which first line prevention and treatment includes vaccines and symptomatic relief that are out of scope. The weighting allocation needs to more accurately reflect the priorities of improving access to essential medicines. Currently, only 4.0% of the total score for each company is attributable to breaches of conduct and litigation in relation to lobbying, marketing, bribery, corruption, clinical trials and anti-competitive behavior. The analysis of the ATMi should incorporate the perspectives of people living in developing countries, and more flexibly consider alternative local approaches rather than prescribing top-down global solutions by for instance acknowledging local generic business unit production.

Greater transparency would strengthen the credibility of results: The ATMi does not disclose indicator level scores unlike other third-party previous attempts to benchmark the pharmaceutical sector, such as the 2006 Interfaith Center on Corporate Responsibility AIDS study. Greater levels of disclosure would facilitate more alignment with alternate third party measures of pharmaceutical sector performance, thereby enhancing the credibility of the ATMi. Disaggregated indicator ratings are important for stakeholders to analyze and validate findings from different vantage points of accountability. The lack of absolute performance transparency can erode the perceived credibility of the ATMi by not facilitating independent validation.

Greater disclosure and analytical tools would more effectively inform stakeholders: More complete and detailed disclosure of company information would make the ATMi a more trusted and complete measure of industry performance. For example, the ATMi did not acknowledge the global advocacy campaign in 12 countries to challenge Abbott Laboratories' monopolistic hold on Kaletra. ATMi reporting of company performance by technical area and company report cards needs to provide more depth, balance and context. Currently, the ATMi focuses on providing performance summaries centered on the two year period under evaluation, without providing further company information depth or supporting external links on its website. Visualization and data analysis tools would enhance the ability of stakeholders to evaluate performance over time across different criteria. Further, the rapid developments across the pharmaceutical sector require more frequent reporting to provide relevant and accurate information to users.

Additional distinct measures would enhance insight on access to essential medicines bottlenecks: A complementary and distinct measure is required to provide insight on the affordability and availability of generic drugs by placing a focus on the level of competition that exists to ensure generic drugs are available, cheap and of sufficient quality. Distribution companies, biotechnology companies, and small and medium sized enterprises represent important industry stakeholders in increasing access to essential medicines that need to be continuously monitored through website industry updates to encourage positive contributions and discourage activities that limit access to essential medicines. An additional index also needs to be developed that evaluates the infrastructure, policies and distribution network of each country in terms of access to essential medicines to draw attention to suboptimal government policies.

b. Policy / research question

This paper explores the role of the pharmaceutical sector in improving access to essential medicines in developing countries and the optimal mechanisms to maximize corporate social responsibility for ensuring innovation and access to meet the public health needs of those in low-income and lower-middle-income countries. While the pharmaceutical sector alone cannot solve the global challenge of access to essential medicines, it represents an important stakeholder and catalyst for positive change. The global pharmaceutical sector is fragmented in terms of market share, production and research and development, presenting a strong opportunity for a scorecard mechanism to standardize and benchmark performance in terms of access to essential medicines. The policy question addressed in this thesis focuses on the Access to Medicine Index (ATMi) as a mechanism to change pharmaceutical practices:

> *Can a global scorecard framework promote a system of public accountability across the pharmaceutical sector to support increased access to essential medicines in developing countries?*

c. Background

The ATMi evaluates one segment of the pharmaceutical sector, originator pharmaceutical companies, in terms of their activities related to access to essential medicines. The objective of the ATMi is to leverage the potential of the pharmaceutical sector in reducing the global burden of disease by promoting greater transparency and objectivity and enhancing multi-stakeholder collaboration. The human right to health is a widely accepted norm that over the last decade has been progressively embraced by the pharmaceutical sector. The ATMi as an actionable governance indicator is attempting to play a catalytic role in positively shaping the pharmaceutical sector by clearly defining and benchmarking practices to societal expectations.

i. Access to essential medicines

Since 1977, the World Health Organization (WHO) has been publishing a model list of essential medicines to guide national governments. The essential medicine list has grown from 204 medicines to 358 in 2011 and it is approximated that 2-6% of the medicines listed

are under patent protection.[4] [5] "The medicines included in the WHO Model List of Essential Medicines are selected with regard to disease prevalence, evidence of safety and efficacy, and comparative cost-effectiveness. As costs of medicines change over time, the price of a medicine is not a reason to exclude it from the WHO Model List if it meets the other stated selection criteria."[6] The small number of patent-protected medicines on the model list may be reflective of the inhibiting factor of cost and ultimately patents and / or the lack of novel, patented medicines with value-added therapeutic efficacy against those diseases comprising the greatest burden of disease; the list "…is replete with antiquated and increasingly ineffective drugs…[and includes]…less than 2 per cent (21) of the 1,377 drugs indicated for global diseases [between 1975 and 1999]"[7]

WHO estimates that 30,000 children die each day from diseases that could be easily treated with a basic range of essential medicines.[8] At least one third of the global population does not have access to medicines, with rates being above 50% for certain developing countries.[9] [10] Factors that limit the delivery of effective, safe and quality medicines when and where needed include: high cost; inefficient distribution; limited health infrastructure; limited health financing; narrow disease focus; inequitable health financing mechanisms; limited research and development pipeline; lack of data and coordination; limited quality controls; and ineffective practices (refer to **Appendix i** for further details on each limitation to access to essential medicines).

ii. The global burden of disease

The global burden of disease is a measure of the impact of disease upon the lives of different populations around the world based on the disability-adjusted-life-year (DALY). DALY captures the loss of the equivalent of one full year of health and is based on a combination of years of life lost due to death and equivalent years of life lost through living in states of less

[4] (WHO, 2012a)

[5] (DFID, 2005 p.20)

[6] (WHO, 2012a)

[7] (Maxwell, 2006 p.71-72)

[8] (WHO, 2009 p.4)

[9] (H. Hogerzeil & Mirza, 2011 p.1)

[10] (DFID, 2005 p.17)

than full health. The Commission on Macroeconomics and Health (CMH) distinguishes three different types of diseases (refer to **Appendix ii** for a definition of Type I, II and III diseases).[11] Diseases can be segmented by geography, communicable versus non-communicable and type (refer to **Appendix iii** for an analysis of the global burden of disease).

iii. The human right to health

The human right to health represents a legal and moral claim against states and transnational corporations, however the field of human rights medicine is generally perceived to be in its infancy. The human rights movement is argued to have only commenced with the Nuremberg trials, with human rights law primarily focused on civil and political rights (refer to **Appendix iv** for further details of the international legal human rights framework).[12]

Transnational corporations are recognized as having human right responsibilities under international law, though a range of voluntary corporate initiatives continue to play an important role in shaping a shared understanding of the right to health.[13] Voluntary international codes of conduct such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Codes of Practice recognize healthcare and wellbeing as being the first priority of pharmaceutical companies.[14] The IFMPA reinforces some elements of the ATMi, specifically pre-approval of communications and promotions and transparency of clinical trials, by monitoring complaints, however the ATMi not only prescribes standards and transparency levels, but also directly evaluates performance reporting. Corporate social responsibility initiatives such as Benefit Corporations (B-Corp) expand the fiduciary duty of corporations to include consideration of the impact of business decisions on workers and communities.[15] Additionally, business coalitions such as GBCHealth, a coalition of over 200 companies committed to leveraging their resources for a

[11] (Sachs, 2001 p.78)

[12] (Farmer, 2003 p.220)

[13] (Wu, 2012 p.98)

[14] (IFPMA, 2012, p. 2)

[15] (BCorps, 2013)

healthier world, foster greater private sector collaboration focused on addressing global health challenges.

iv. Pharmaceutical sector response to access to essential medicines

Over the past decade, multinational pharmaceutical companies have been more active in the neglected disease field. The greater focus on neglected diseases can be attributed to growing public awareness of unmet developing country health needs, the establishment of dedicated institutes by multinational companies and new public-private partnerships financed by an influx of public and philanthropic funds.[16] Organizations such as Oxfam, Save the Children, VSO, Health Action International, WHO and Médecins Sans Frontières have played an important role in drawing global attention to the issue of essential medicine. Responses by the pharmaceutical industry have included greater investment in neglected disease research, developing country investment, collaborative product development, improving health care delivery systems, differential pricing, patent sharing and voluntary licensing and donations. Pharmaceutical responses however have not always resulted in positive impacts; donation programs can undermine markets and competition and differential pricing programs can be difficult to benchmark absent generic competition, lower tiered prices may still be higher than the marginal cost of manufacturing and affordability levels may still be less than the marginal cost of manufacturing (refer to **Appendix vii** for further details on the changes in the practices of pharmaceutical companies in providing access to medicine and details on their implications).

v. The access to medicine responsibility of the pharmaceutical sector

The corporate responsibility for second-order consequences or negative externalities of global operations has rapidly evolved. In the 1990s, significant public attention was placed on the overseas manufacturing conditions of companies connected with Nike and the Walt Disney Company, as examples. Attention was particularly focused on the athletic footwear, apparel, retail and toy industries, which had high concentrations of sweatshops and human right abuses.[17] Corporate responsibility has since been evolving to address not only the negative impacts of what a company does, but also the consequences of what a company

[16] (Mary Moran, Ropars, Guzman, Diaz, & Garrison, September 2005 p.8)

[17] (Sethi, 2003 p.28)

does not do. The rise of corporate philanthropy is a reflection of the importance of positive contributions to society to retain talent, strengthen brand, generate innovation and expand markets and business relationships.[18]

The pharmaceutical industry is an example of one sector for which societal expectations are extending beyond minimum ethical standards of practice (refer to **Appendix viii** for an analysis of pharmaceutical sector activities considered important in enhancing access to essential medicines). In fact, societal expectations are extending beyond the making of ethical profits, to intentionally limiting profits to satisfy society's needs. Pharmaceutical companies are perceived as having a special duty to provide aid in the way of essential medicines by virtue of the moral character of health-care needs, health as a human right and their unique capacity to render aid.[19] Arguably, entities involved in the medical field incur certain unique responsibilities because of the role they play in sustaining the quality, security and integrity of lives.[20] Physicians, for example, are expected to provide emergency care even when inconvenient and it puts them at risk.[21]

> "One important counter-argument to this is based on the idea that shareholders in pharmaceutical companies have a claim to the profits by agreement, and by the duty of loyalty. It is difficult to imagine, however, that the duty to maximize shareholder profits could override the duty to save lives, especially in the face of a right. Rights, after all, trump considerations of utility…[Pharmaceutical companies] are subject to…two distinct sets of fiduciary duties: those of managers to shareholders, and indirectly, the fiduciary duties of physicians to their patients…Patients are dependant on pharmaceutical companies for their life, security and welfare, at least as much as they depend on the physician." [22]

The pharmaceutical sector is comprised of originator pharmaceutical companies, generic manufacturers, biotechnology companies, distributors and small and medium sized enterprises, existing either independently or in a hybrid form (refer to **Appendix vi** for a detailed analysis of the pharmaceutical industry and its segments). Each sector of the

[18] (Levy, 1999)

[19] (Forman & Kohler, 2012 p.75)

[20] (Forman & Kohler, 2012 p.79)

[21] (Forman & Kohler, 2012 p.79)

[22] (Forman & Kohler, 2012 p.80-81,84)

pharmaceutical industry plays a unique and important role in providing access to essential medicines. Initiatives that attempt to change industry practices need to be targeted to specific segments to maximize the impact of limited resources. For example, improving access to branded medicines requires a focus on the transparency of research, patents, distribution and prices, however improving access to generic medicines requires a focus on promoting competition. The University Global Health Impact Report Cards represents one targeted approach that attempts to measure and shape the impact of university policies on global health.[23]

vi. Catalyzing industry change through governance by transparency

The ATMi, as an actionable governance indicator (AGI), can play an important role in defining societal expectations of an industry consisting of opaque activities and operating across diverse business models (refer to **Appendix ix** and **x** for an analysis of different industry change mechanisms with corresponding examples). AGIs aggregate information from different sources into a format intended to holistically capture and benchmark performance to empower user decision-making. AGIs distill and standardize complex data into simple ratings and present the information in a format designed to be user-centered, allowing performance to be understood, compared and acted upon.[24] AGIs however can involve a degree of subjectivity in the weightings and measures applied which can limit the ability to action results when not supported by full transparency (refer to **Appendix xi** for an analysis of leading AGI practices). Additional examples of AGIs include the Carbon Disclosure Project (CDP), World Bank 'Doing Business' (DB), Freedom House 'Freedom in the World' (FIW), Aid Transparency Index (ATI), and Transparency International 'Corruption Perceptions Index' (CPI). The CDP, DB, FIW, ATI, and CPI report on an annual basis as compared to the ATMi that reports on a bi-annual basis. The DB, ATI and CPI reveal source data and full disaggregated scores, the CDP reveals its source data but no disaggregated scores, while the FIW and ATMi reveal no source data and only partially disaggregated scores.

[23] (UGHI, 2013)

[24] (Fung, Graham, & Weil, 2007, p. 2)

Transparency and public activism today represent increasingly important industry governance mechanisms, connected with the rapid development of technology and data management platforms. The internet and mobile devices allow users to access an unprecedented level of knowledge almost anywhere, however information disclosure alone is not driving change. Effective targeted transparency policies embed new information into users' and disclosers' existing decision making routines, based on an understanding of their diverse priorities and capacities, to enable action.[25] Restaurant hygiene quality cards in Los Angeles have been highly embedded in consumer dining decision making by assigning a simple letter grade at the front of restaurants, whereas material safety data sheets intended to disclose workplace chemical hazards have not been as effective due to their complex nature.[26] Targeted transparency can mobilize "…individual choice, market forces and participatory democracy through relatively light-handed government action."[27]

vii. The Access to Medicine Index

The Access to Medicine Index (ATMi) was launched in 2008 by the Access to Medicine Foundation (ATMf), a Dutch based international non-profit organization. The purpose of the ATMi is to encourage the pharmaceutical industry to improve access to medicines. The index is intended to provide a reliable, independent and impartial evaluation of the performance of pharmaceutical companies across several dimensions (refer to **Appendix xii** for further details on the ATMi and the results in 2010 and 2012).

The ATMi is building momentum and credibility. In 2008, nine of the 17 originator firms and none of the three generic firms responded to data requests.[28] By 2010, 19 of the 20 originator companies and three out of seven generic companies responded to the ATMi.[29] Recently, the Bill & Melinda Gates Foundation committed to providing $2,952,852 over four years in addition to the $1,095,018 provided in 2009, the Dutch Ministry of Affairs committed to a five-year grant, and the British Department for International Development

[25] (Fung et al., 2007, p. xiv)

[26] (Fung et al., 2007, pp. 57-61)

[27] (Fung et al., 2007, p. 5)

[28] (AMI, 2010, p. 16)

[29] (AMI, 2010, p. 16)

committed to a four-year grant.[30] The ATMf declined a request as part of this study to reveal the level of grant funding it has received.

d. Research Methodology

The analytical strategy for this paper consists of a combination of literature reviews, case studies and interviews. Personal interviews and survey tools were utilized to obtain a sample of perspectives across global health organizations, human rights organizations focused on developing country issues, investors and the pharmaceutical sector (refer to **Appendix xiii** for further details on the interview / survey questions and **Section K** for the acknowledgement of study participants). This paper focuses on analyzing the effectiveness of the ATMi as a mechanism to improve access to essential medicines. The scope and methodology of the ATMi is reviewed, findings benchmarked and its impact analyzed.

i. ATMi scope and methodology

Various industry change initiatives are analyzed to place in context the role of actionable governance indicators in facilitating change. Different examples of actionable governance indicators are analyzed to identify leading practices and to provide an objective framework for evaluating the ATMi. The scope and methodology of the ATMi is assessed in terms of alignment to the objective of measuring, comparing and standardizing pharmaceutical practices in order to improve access to essential medicines. Consideration is provided to the theory of change, user centered policies, specified targets, scope and structure, completeness of indicators, transparency, complementary measures, measurement errors, comparison of performance over time, prioritization and completeness and accuracy.

Alternative potential frames of focus are considered in light of market share, regional focus, donation and research and development tax deduction and credit benefits, potential versus actual capacity, upstream versus downstream interventions, pre-competitive versus competitive research and development, and people served. Consideration is also provided to collective versus individual measures of company capabilities and performance.

[30] (AMI, 2012a)

ii. ATMi findings

ATMi scores and findings are benchmarked on a sample basis to confirm completeness and accuracy. The benchmarking exercise is limited by the lack of full transparency of the underlying data of the ATMi and the lack of public information on the activities of the pharmaceutical sector. Benchmarking resources include media reports (e.g. ABN/INFORM Complete, Factiva and Lexis/Nexus Academic), databases (e.g. G-Finder and Global Socrates - Corporate Social Responsibility), and third party monitors (e.g. Center for Political Accountability). ATMi pharmaceutical company performance scores are correlated to other third party performance evaluators by comparing approach and rakings, including the Pacific Sustainability Index (PSI), the Interfaith Center of Corporate Responsibility (ICCR) Benchmarking AIDS and Oxfam's Investing for Life. Gaps in publicly available information necessary to evaluate access to essential medicines performance across the pharmaceutical sector are additionally noted.

iii. ATMi impact

An evaluation is performed of the resonance of the ATMi across the civil sector including human rights and global health organizations, investors, pharmaceutical companies and the public / consumers. The analysis consists of interviews as well as a review of share price movements, press releases, web search-engine activity, annual reports and corporate social responsibility reports, websites and media reports and articles. A focus is made on identifying changes in the activities of companies attributable to the ATMi. The analysis includes an evaluation of the effectiveness of stakeholder engagement and consensus building.

e. Analysis and Findings

i. ATMi is shaping pharmaceutical practices, but continued impact is uncertain

The objective of the ATMi is to "…stimulate positive change by publicly encouraging pharmaceutical companies to step up their efforts to improve access to medicine worldwide [by supporting] the pharmaceutical industry on a path towards greater transparency, to allow companies to develop best practices in access to medicine and to present the outcomes to the

outside world."[31] Positive changes have been observed across the pharmaceutical sector in response to the ATMi, however the momentum developed and the extent of change observed to date has been limited.

Pharmaceutical companies do appear to be responding to the ATMi; however, changes have been limited

Pharmaceutical companies do appear to a limited degree to be directly responding to the ATMi based on an analysis of changes between 2010 and 2012, however attribution is not conclusive in the absence of public affirmations by companies of their responses to the index (refer to **Appendix xxx** for more detail on the changes in company performance from 2010 to 2012 as formally acknowledged by the ATMi in the Access to Medicine Index 2012). Although other civil sector organizations focused on access to essential medicines may be driving some of the industry changes observed, limited interviews and surveys conducted as part of this study affirmed that certain companies were directly responding to the ATMi. The New York Times further noted in April 2013 that pharmaceutical companies were no longer ignoring the ATMi by naming executives to ensure they excelled in the index.[32] In terms of general access to medicine management, GSK, J&J, Sanofi, Merck KGaA and Eisai were noted to have created a business unit dedicated to access and / or introduced board-level engagement. For public policy and market influence, GSK, J&J, Novo Nordisk, Novartis, Bristol-Myers, Gilead, Eisai and Eli Lilly strengthened their codes of conduct, although GSK, J&J and Eli Lilly were also responding to litigation related to recent ethical breaches. In terms of research and development, Sanofi, Merck KGaA and Eli Lilly commenced either adaptive and / or innovative research for the poor, J&J and Daiichi Sankyo acquired large generic developers, and GSK, Merck, Novo Nordisk, Novartis, Roche, Eisai, Boehringer-Ingelheim, Takeda and Astellas expanded their related research pipeline. Regarding pricing, manufacturing and distribution, GSK, Sanofi, Bayer, Pfizer, Eisai and Daiichi Sankyo (all not previous members of the Accelerating Access Initiative) introduced intra- and / or inter-country pricing schemes and J&J and Merck KGaA disclosed more information on their tiered pricing program. In terms of patents and licensing, J&J, Sanofi, Bayer, Merck and

[31] (AMI, 2012a)

[32] (McNeil, 2013)

Boehringer-Ingelheim increased the degree of disclosure in support of TRIPS flexibilities and / or in flexibly enforcing patents in developing countries and GSK, J&J, Merck and Gilead Sciences issued additional non-exclusive voluntary licenses. However, not all patent and licensing changes were positive, with J&J withdrawing from the Medicines Patent Pool negotiations, Merck, Novartis and Bayer contesting patent rights in developing countries, and Eisai, AstraZenca and Astellas not following through on prior commitments in 2010 to either issue non-exclusive voluntary licenses or to not enforce patents in least developed countries. Regarding capability advancement in product development and distribution, GSK, J&J, Novo Nordisk, Merck KGaA, Abbott, AstraZenca, Boehringer-Ingelheim, and Takeda were noted to have created new capacity building partnerships. In terms of product donations and philanthropic activities, Gilead Sciences, Novo Nordisk, and Eisai introduced single-drug donation programs and GSK and Sanofi significantly expanded their philanthropic activities.

Pharmaceutical company public recognition / acknowledgement of ATMi is improving but sill limited

Public recognition of the ATMi by pharmaceutical companies is growing but still considered limited (refer to **Appendix xxviii** for the analysis of public recognition of the 2010 and 2012 ATMi results in the corporate websites and annual / corporate responsibility reports of pharmaceutical companies included in the index). For the 2010 ATMi, three companies acknowledged their ATMi ranking and three acknowledged the existence of the ATMi either within their annual or corporate responsibility report. For the 2012 ATMi, seven companies acknowledged the index results, all ranked within the top nine of the index: the top ranking company provided a CEO press release; four included a Vice President press release / statement and two included web site ranking acknowledgements. Only one company in the ATMi that fell in ranking in 2012 acknowledged the index on their website. The eleven bottom ranked companies in the ATMi did not acknowledge the index results in 2012.

ii. ATMi is not optimally meeting its objective of promoting multi-stakeholder dialogue

The objective of the ATMi in terms of stakeholders is "…to supply pharmaceutical companies, investors, governments, academics, non-governmental organisations and the

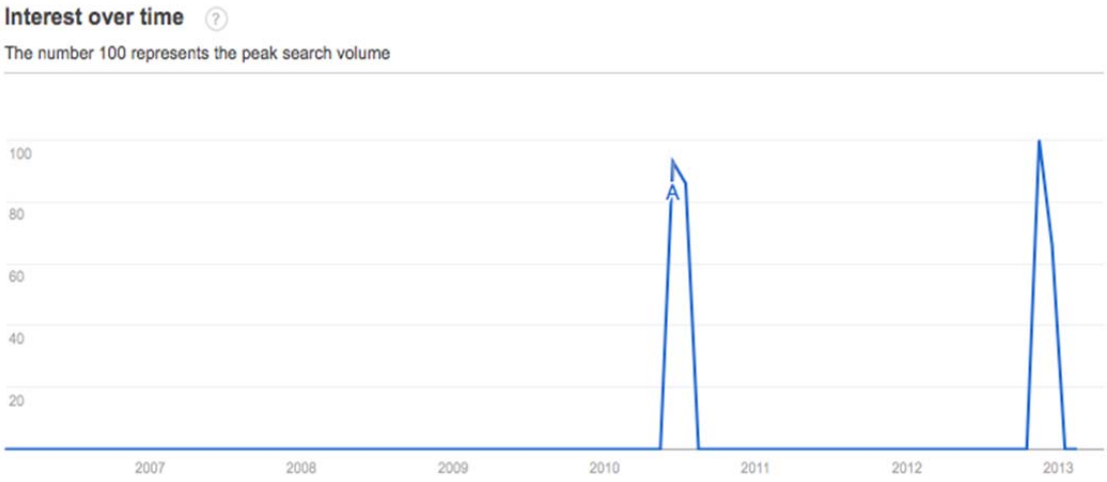
general public with independent, balanced and cohesive information on individual pharmaceutical companies' efforts to improve global access to medicine…to provide pharmaceutical companies with a transparent means by which they can assess, monitor and improve their own performance and their public and investment profile [to] raise awareness of relevant issues within pharmaceutical companies and allow other stakeholders to follow the industry's progress [and to] highlight industry trends and provide a basis for multi-stakeholder dialogue and solution-building."[33] Pharmaceutical companies may be responding to the index, however the level of competitive advantage gained is questionable based on an analysis of investor and public response to the index to date. Dispersed users of the information generated by the ATMi do not appear to be forming political coalitions to press effectively for better disclosure and performance.

Public engagement is limited in concentration and breadth based on analysis of web search volume

An analysis of Google Trends for the search volume associated with 'Access to Medicine Index' reveals that public interest in the ATMi is concentrated for a short period surrounding the publication of the bi-annual index, with interest increasing marginally since 2010. The concentrated volume over short periods could be attributed to the ATMi not explicitly targeting consumers / public over time with updated industry sector information. The ATMf has adopted Twitter and LinkedIn and is exploring other social media tools to promote greater public engagement. It is acknowledged that the ATMi actively engages in discussions of index results at conferences, lectures and other events.

[33] (AMI, 2012a)

Figure 1: Search volume trends over time associated with 'Access to Medicine Index'



Source: Google Trends, February 2013

Media reports are growing but only marginally over time

The global media attention surrounding the ATMi was small and concentrated in 2008 and has increased marginally since, peaking with the release of each index (refer to **Appendix xix** for the count of media reports containing 'Access to Medicine Index,' excluding social media). An analysis of media reports including social media similarly notes a concentration of interest across blogs and twitter in the week following the release of the index (refer to **Appendix xx** for the count of media reports containing 'Access to Medicine Index' including social media). Evidence was noted that the ATMi is establishing public credibility; IDEA Pharma as part of its annual Productive Innovation Index rated Johnson & Johnson first partially due to the company's placement in the ATMi.[34]

Investor response is weak with no relationship observed between ATMi and share price

There does not appear to be any relationship between ATMi rankings and share price movements to date, which may reflect the need for more time for the ATMi to gain acceptance and credibility in capital markets. The following analysis consists of general rather than statistically significant observations, as the analysis was limited to only three data points for 2008, 2010 and 2012. In 2008 no consistent and significant movements were noted in the share prices of the five best and worst ATMi performers immediately after the

[34] (Grogan, 2013)

index was released, although share prices improved for four of the five best performers and three of the five worst performers two weeks after publication (refer to **Appendix xxi & xxii** for the indexed share price movements of the best and worst ATMi performers in 2008). In 2010 no consistent and significant movements were noted in the share prices of the three best performers and two best improvers, and the three worst performers and two worst decreases, immediately after the index was released, although share prices generally decreased more for the best performers two weeks after publication (refer to **Appendix xxiii & xxiv** for the indexed share price movements of the best and worst ATMi performers in 2010). In 2012 no consistent and significant movements were again noted in the share prices of the three best performers and two best improvers, and the three worst performers and two worst decreases, immediately after the index was released, with almost all share prices increasing two weeks after publication (refer to **Appendix xxv & xxvi** for the indexed share price movements of the best and worst ATMi performers in 2012).

An analysis of the share price movements of the four top and four worst performers of the ATMi since 2008 suggests greater market returns for companies consistently ranked higher in the index (refer to **Appendix xxix** for the indexed share price movements of the top four and worst four ATMi performers since 2008). However, Merck & Co is a noted exception with its share price performing generally worse or consistent with two of the lowest ranked companies in the ATMi. Additionally, correlation is not necessarily causation, evidenced by the lack of consistent and significant share price movements in response to each ATMi release.

The ATMi is building an investor community receptive to the importance of access to essential medicines. In December 2012 the ATMf presented the 2012 ATMi findings to the 50 top pharmaceutical analysts at three meetings, hosted by Goldman Sachs in London, Amundi Asset Management in Paris and MSCI ESG Research in New York. In June 2011 29 investors with USD $3.7 trillion under management agreed that access to medicine is potentially material to long-term shareholder value creation and to consider the ATMi as appropriate in their ESG analysis. An attempt was made to identify the proportion of assets specifically allocated to the pharmaceutical sector by the 29 committed investors, however this information was not publicly accessible.

Civil sector groups do not appear to be leveraging index results

Civil sector does not appear to be publicly engaging and leveraging the ATMi over time. A search was performed of a sample of civil sector websites and a Google search was additionally performed (combination of the name of each organization with 'Access to Medicine Index') to identify links to past ATMi reports and an analysis of ATMi results (refer to **Appendix xxvii** for the analysis of civil sector recognition of ATMi results). Of 26 civil sector organizations sampled that focused on global health and/or human rights in developing countries, only four and one referenced the 2010 and 2012 index reports respectively. Only three organizations were noted to have publicly analyzed the ATMi's findings, Health Action International provided a critique in 2008, Oxfam analyzed the 2010 results and Pan American Health Organization referenced a related BBC article.

f. Recommendations

i. Simplifying the measurement framework would enhance stakeholder understanding

Specifying higher standards of performance would simplify measurement and more effectively differentiate practices

Specifying higher standards of performance would further differentiate practices and reduce the number of indicators required (refer to **Appendix viii** for the pharmaceutical activities considered important in enhancing access to essential medicines and **Appendix xvii** for the results of the ATMi indicator evaluation). Higher standards of performance would negate the need for indicators related to the 'Innovation' strategic pillar, which serve only to award companies additional points for leading practices. Best practices that receive maximum scores should include; more onerous reporting requirements such as actual drug prices by product rather than average prices in the lowest and highest pricing tiers (e.g. ATMi indicators A.II.1 and D.II.2); compliance with leading standards such as the International Standards for Clinical Trial Registries and WHO Guidelines for Good Clinical Practice (e.g. C.II.4 and C.III.9); coverage of the full scope of diseases and countries rather than only a portion (e.g. B.II.1, D.III.1 and E.I.1); greater levels of public disclosure such as in terms of

promotional and marketing policies, activities and costs rather than only requiring disclosure to the ATMi (e.g. B.II.5 and C.II.1); higher ethical performance standards such as requiring marketing approval and product registration before product launch rather than up to 12 months after product launch (e.g. A.III.2, D.I.6 and G.III.4); and indefinite rather than time-bound commitments to eradicating targeted disease(s) (e.g. F.III.2, F.III.3, Fi.III.4 and F.III.5). Additionally, it would be more strategic to fully recognize negative practices, whether anti-competitive or unethical, even when they do not occur in index countries, as they reflect a failure of governance systems that the ATMi is attempting to evaluate (e.g. B.III.2). A global perspective to negative practices also recognizes that enforcement might only be possible in industrialized countries with stringent drug regulatory authorities, despite the possibility of a wider pattern of practice by such companies in miss marketing where there might be laxer regulatory standards. Currently, ethical and legal breaches are only recognized in index countries and this has resulted in the exclusion from the 2012 ATMi of the criminal misdemeanor charges and USD 3 billion settlement by GSK in the US.[35] [36]

The ATMi should consider as an alternative, but not necessarily adopt, finalizing and publishing its scoring scale in advance of seeking company submissions to provide a clearer and more consistent signal of best practices. The ATMi finalizes the scoring scale for each indicator subsequent to the review of submissions by companies in order to seek a balanced distribution of performance. Setting a scoring scale based on the review of company submissions could limit the comparability of performance over time, distort the true absolute level of performance and provide companies with insufficient signals of best practices to strive for.

The ATMi is encouraged to continue to experiment with indicators that measure outcomes and impacts and place less emphasis on outputs to more effectively differentiate performance. For example, currently a number of indicators place a focus on outputs: A.I.2 rewards the number of outreach activities; A.III.2 the number of reputable conferences hosted; C.III.4 the number of product development collaborations; F.III.1 the number of training workshops; F.III.2 the number of local public sector research partnerships; and

[35] (AMI, 2012a, p. 111)

[36] (Ingram, 2012)

F.III.3 the number of government partnerships. An important outcome measure as a proxy for affordability and availability currently not included in the ATMi is the public disclosure of unit sales by drug and country. This paper acknowledges that unit sales are influenced by a number of factors, not all controllable by pharmaceutical companies. In addition, unit sale increases in a country do not guarantee that medicines are reaching the most disadvantaged communities. However, unit sales represent one important data element, which when combined with country level needs and funding data, could help to make the impact of company access policies more transparent. An additional outcome measure not included in the ATMi relating to in-country perceptions of drug availability, pricing and rational use is further discussed in the next section.

Further standardization would more effectively align measures and simplify the analysis of company strengths and weaknesses

The ATMi should standardize the nature and requirements of indicators to consistently measure the adequacy of commitments, transparency and performance in relation to the technical activities in scope. Every theme for each technical area should be associated with a measure of commitment, transparency and performance. For example, indicator D.I.3 confirms commitments by pharmaceutical companies to control pricing practices of local sales agents, however currently this theme is not associated with a measure of transparency or performance (refer to **Appendix xiv** for the analysis of each technical area theme across measures of commitment, transparency and performance). The ATMi should further reallocate particular indicators across technical areas to enhance alignment of measures. For example, indicators A.I.2 and A.III.2 relating to engaging with different stakeholder groups and further detailed below would be better aligned with capability advancement in product development and distribution instead of general access to management.

A.I.2 The company commits to work with relevant stakeholders including universities, patient groups, local governments, employees, local and international NGOs and peers with the aim of improving access to medicines.
5 The company has a strategy and platform for outreach to >10 relevant stakeholder groups for 3 relevant initiatives.
4 The company has a strategy and platform for outreach to relevant stakeholder groups for 3 relevant initiatives.
2.5 The company has a strategy and platform for outreach to relevant stakeholder groups for 2 relevant initiatives.
1 The company has a strategy and platform for outreach to relevant stakeholder groups for a relevant initiative.
0 The company has no relevant stakeholder engagement.

A.III.2 Senior management participates in public debate and engages with the different stakeholder groups with the goal of dialogue and knowledge sharing aimed at improved access to products for the Index Diseases in the Index Countries (measured through sponsoring and participating in relevant conferences, workshops, etc.).

5 The company hosts or plays a significant role to disseminate knowledge (agenda development role/organizing committee/lead sponsor) in >15 reputable conferences/symposia.*

4 The company engages in 5-15 of the above.

2.5 The company engages in 2-5 of the above.

1 There is no evidence of more than 1 of the above.

0 The company does not provide evidence of the above.

Indicators B.1.4 and B.II.5 relating to ethical marketing practices and further detailed below would be better aligned with manufacturing and distribution instead of public policy and market influence.

B.I.4 The company commits to enforce a code of conduct regarding ethical marketing practices for all sales agents and local third party* distributors and contractors consistent with its own internal standards.

5 The company has processes in place to monitor marketing practices and enforce ethical marketing codes of practice by all its sales agents in the relevant countries which includes auditing of the agents' practices.

2.5 The company has specific ethical marketing codes of practice for all its sales agents in the relevant countries, but no auditing (monitioring or enforcement) mechanisms.

0 The company makes no provisions with regards to the marketing behaviour of the local sales agents.

B.II.5 The company discloses detailed information regarding its marketing and promotional programmes in the Index Countries, such as payments to or promotional activities directed at physicians or other key health care professionals or opinion leaders.

5 The company discloses detailed information related to drug promotion in areas such as payments to physicians and methods for incentivising health care providers, pharmacies etc. in the relevant countries.

2.5 The company discloses its approach without regularly disclosing exact contribution figures and performance information in this area (including aggregate data but no details).

0 The company makes no disclosure in this area.

Indicators C.I.3, C.II.2, and C.III.8 relating to intellectual capital management and further detailed below would be better aligned with patents and licensing instead of research and development.

C.I.3 The company commits to ensuring equitable access to products successfully developed through R&D partnerships.

5 The company systematically applies principles of socially responsible and humanitarian licencing in the relevant countries in relation to the intellectual property generated in public private partnerships and PDPs for relevant diseases (i.e. either waives all rights over the IP generated or explicitly encourages affordable, timely and high quality supply to relevant populations).

2.5 The company systematically applies principles of socially responsible and humanitarian licencing in relation to the intellectual property generated in public private partnerships and PDPs for a subset of relevant diseases in only a subset of the relevant countries.

0 The company makes no commitments in this area.

C.II.2 The company discloses the licencing details pertaining to its research collaborations related to the Index Diseases (with regard to Intellectual Property rights, access provisions etc.).

5 The company publicly discloses the existence and mandate of all relevant collaborations plus licencing details in relation to the duration of engagements, company's obligations, delivery milestones, march-in clauses and IP rights (such as supply channels, territory, disease scope, pricing, delivery timescales, royalties or other payment structures).

4 The company carries out a full public disclosure of the existence and mandate of the majority of its relevant collaborations plus partial licencing details relating to at least one of its collaborations.

3 The company publicly discloses the existence and mandate of most of its relevant collaborations or provides examples of its licencing details.

2 The company discloses licencing details at 4 or 5 level on an engagement basis only.

1 The company discloses licencing details at the level of 3 only on an engagement basis only.

0 The company makes no disclosure in this area.

C.III.8 The company provides evidence of sharing its intellectual capital (e.g., molecules library, patented compounds, processes or technologies) with research institutions and neglected disease drug discovery initiatives (e.g. WIPO Re: search, CDD, OSDD) that develop products for Index Diseases on terms most conducive to access for the Index Countries.

0-5 Total number of instances of company providing third-party access to its relevant disease-related intellectual property during the survey period divided by total company revenue in 2010 and 2011. This number was scaled across all companies to achieve a revenue-standardized score. Companies who engaged in intellectual capital sharing received a score between 2.5 and 5. Companies who did not provide any evidence of sharing received a 0.

More specific and verifiable measures would improve the ability of stakeholders to understand and trust the ATMi evaluation framework

ATMi indicators could be more specific and verifiable to foster greater levels of credibility and transparency (refer to **Appendix xviii** for the results of the evaluation of each 2012 indicator). 30% of the 101 indicators were considered not adequately specific, as they did not always detail what evidence of pharmaceutical companies was to be provided, to whom, and how often, as applicable. Examples of indicators not being specific that are further detailed below include B.II.2 (not clear to whom and how often political contributions need to be disclosed) and B.II.5 (not clear to whom disclosure is required).

B.II.2 The company discloses any potential governance conflict of interests and/or interest groups or institutions it financially supports, through which it might advocate its public policy positions at regional, national or international levels where relevant to access to medicine in the Index Countries.

5 The company makes detailed transaction level disclosure on lobbying payments to different stakeholders with specific Index country reporting.

4 The company makes detailed transaction level disclosure on lobbying payments to different stakeholders but no specific Index country reporting.

2.5 The company has partial disclosure in this area, supplying aggregate figures only.

0 The company makes no disclosure in this area.

B.II.5 The company discloses detailed information regarding its marketing and promotional programmes in the Index Countries, such as payments to or promotional activities directed at physicians or other key health care professionals or opinion leaders.

5 The company discloses detailed information related to drug promotion in areas such as payments to physicians and methods for incentivising health care providers, pharmacies etc. in the relevant countries.

2.5 The company discloses its approach without regularly disclosing exact contribution figures and performance information in this area (including aggregate data but no details).

0 The company makes no disclosure in this area.

55% of indicators did not adequately detail the source and nature of evidence used for verification to facilitate independent validation. Examples of indicators not being verifiable that are further detailed below include C.III.2 (not clear what basis was used to calculate 10% of pipeline; number in pipeline, investment dollars, etc.) and D.I.6 (not clear what evidence was used; whether third party product registry, company internal listing, etc.)

C.III.2. Share of research pipeline reflecting 'new molecules' for Index Diseases including in-house and collaborative research. For companies that have multiple Index disease focus.

5 Share of pipeline is >10% dedicated to new molecules for relevant diseases.

4 Share of pipeline has 5-10% dedicated to relevant diseases.

3 Share of pipeline has <5 % dedicated to relevant diseases or more then 50% with only one or two relevant disease focus.

2 The company has not provided any molecules in its pipeline for relevant diseases but we have discovered examples of such molecules through research of publicly available information.

0 The company has no molecules/activity with respect to R&D for relevant diseases.

D.I.6 The company commits to file for marketing approval or product registration of its products for the Index Diseases in the Index Countries in need.

5 The company has specific targets to register all products for relevant diseases in all of Sub-Saharan Africa and all other Low-Income Countries and Low and Middle Income Countries within 12 months of market launch.

2.5 The company has committed to register a sub-set of its products for relevant diseases in all of Sub-Saharan Africa, Low-Income Countries and Low and Middle Income Countries but has not committed to a timeframe.

0 The company makes no commitment to register its products for the relevant diseases in the relevant countries.

ii. Strengthening the measurement framework in terms of measures, weighting and focus would enhance accuracy and completeness of findings

Additional measures would provide for more complete and accurate measure of pharmaceutical performance

The ATMi should analyze additional measures to more completely and accurately capture the performance of pharmaceutical companies (refer to **Appendix viii** for the pharmaceutical sector activities considered important in enhancing access to essential medicines and **Appendix xvii** for the results of the ATMi 2012 indicator evaluation). One category of missing measures relates to the need for companies to disclose more information on current practices, such as in relation to ethical promotion complaints, adverse drug reactions, joint public private initiative governance transparency and conditions, and donation tax benefits derived. A second category of missing measures relates to the need for higher levels of ethical practices, such as not utilizing transfer pricing practices for tax avoidance purposes, transparent product labeling and distribution traceability, compliance with international manufacturing standards, active drug safety monitoring, responsible patenting of traditional medicines and designing packaging to suit local environment conditions and address counterfeiting. A third category of missing measures relates to practices that can accelerate the availability, accessibility and affordability of essential medicines, including pricing practices that are affordable to the majority of populations in developing countries, expanding research into pediatric formulations, not lobbying for stronger intellectual property rights in relation to the Trans-Pacific Partnership Agreement and seeking drug approval in non-US markets prior to approval from the US Food and Drug Administration

(FDA) and the EU's European Medicines Agency (EMEA). As an example, GlaxoSmithKline's launch of Rotarix, a new rotavirus vaccine, in Mexico in 2005 that was subsequently approved by the FDA in 2008 and over 100 other countries demonstrates the benefit of accelerated approval in non-US markets, however foreign markets must have strong drug regulatory bodies to not expose the public to unnecessary risks.[37] [38] This study acknowledges the limitations of being too prescriptive in the definition of indicators, which need to also be flexible so that measures remain relevant and comprehensive without the need for regular revisions. Flexibility in indictor definitions, with a focus on intent to promote access to essential medicines, would ensure the capture of all relevant activities such as Eli Lilly's recent efforts to establish that Canada's denial of one of their patents for an attention-deficit disorder drug as valid constitutes a form of takings and warrants USD 100 million in compensation.[39]

Greater consistency in disease and medicine focus would ensure limited resources of ATMi are most effectively targeted

The ATMi understandably limits the scope of diseases, medicines and countries to focus attention on areas with the greatest potential for impactful change, however greater consistency is required across in-scope and out-of-scope elements to effectively leverage resources. For example, the ATMi includes in its disease scope tetanus and measles for which first line prevention includes vaccinations, and treatment includes medicines for symptomatic relief; however, vaccines and medicines for symptomatic relief are excluded from the index scope. The ATMi identifies the priority diseases based on an analysis of the global DALY burden today. An alternate analysis of the global disease burden specific to LICs and LMICs currently and in 2030 noted some variances, however this study acknowledges the subjective nature of selecting diseases in-scope based on a multitude of factors evaluated by the ATMi expert stakeholders (refer to **Appendix xv** for the results of the DALY analysis in comparison to the ATMi and **Appendix xvi** for the projected DALY impact in 2030). Rather than prescribing the diseases or medicines that should be in scope,

[37] (Braine, 2005)

[38] (Ward, Bernstein, & Plotkin, 2009)

[39] (Gray, 2012)

this study recommends that there should be greater alignment with the in-scope and out-of-scope elements of the ATMi.

Strengthening the weighting allocation would place a greater focus on activities important in improving access to essential medicines

The weighting allocation across the ATMi needs to be more reflective of the priorities to improving access to essential medicines. Currently, only 4.0% of the total score for each company is attributable to breaches of conduct and litigation in relation to lobbying, marketing, bribery, corruption, clinical trials and anti-competitive behavior (indicators B.III.1, B.III.2 and C.III.7). The policy position in terms of TRIPS, data exclusivity and the Medicine Patent Pool is apportioned only 3.0% (indicators E.II.1, E.III.5 and B.II.4), 0.5% (indicator B.I.3 and B.II.4) and 1.2% (indicator E.III.3) respectively of the total company score. In contrast, non-binding and not necessarily public commitments currently represent a quarter (25%) of a company's entire score, equal to the weighing applied to indicators focused on promoting transparency. Although internal governance structures, codes of conduct and policies and procedures are important, a greater weight should be applied to transparency and performance reporting, with a greater emphasis on the themes mentioned above.

A greater focus on outcomes would more accurately differentiate company practices

The analysis of the ATMi would be strengthened by evaluating evidence and incorporating studies that focus on the perspectives of people living in developing countries, particularly in terms of drug availability, pricing and rational use. The ATMi analysis currently focuses on information submitted by pharmaceutical companies that is verified against third party sources. However, the price set by a pharmaceutical company, quantity shipped to a country and recorded sales volumes provide only limited assurance that the final sale price of medicines was affordable, accessible and available to disadvantaged communities and facilitated rational use. Surveys of health professionals, patients and community members in developing countries, similar to studies conducted by WHO / Health Action International Project on Medicine Prices focused on promotional activities and prices, should be

performed across a subset of in-scope countries and supplement company evaluations.[40] Transparency International's Corruption Perception Index (CPI) represents an example of utilizing the perceptions of diverse sources to derive an average absolute score. This study acknowledges the limitations of perception-based indices as observed for the CPI; by influencing and being influenced by the perceptions on which they are based through the effects of media, perception-based indices may not always reflect reality and may be associated with large margins of error.[41]

The evaluation criteria of the ATMi needs to be flexible in considering alternative local approaches to improving access to essential medicines, rather than prescribing top-down global solutions. For example, the ATMi currently places an emphasis on global tiered pricing policies, non-exclusive voluntary licenses and non-assert declarations, but has excluded consideration of generic business units of originator companies. As further detail, the 'Manufacturing and Distribution' strategic pillar of the ATMi focuses on inter- and intra-country tiered pricing across all products and relevant countries, but this may not be a viable strategy for a company with a generic business unit. It is acknowledged that generic business units were excluded due to a miscommunication between the ATMf and pharmaceutical companies as to the in-scope nature of generic drug manufacturers. Companies should be evaluated on their individual approaches to enhancing access to essential medicines based on the availability, affordability and accessibility of their relevant product portfolio in index countries.

iii. Greater transparency would strengthen the credibility of results

ATMi level of disclosure is less than alternative pharmaceutical benchmark studies, undermining intention to promote greater transparency

The ATMi has a number of strengths when compared to alternate benchmark approaches in measuring the performance of the pharmaceutical sector, however it is weaker in terms of scoring transparency. An analysis was performed of the methodologies and results of past alternative benchmarking exercises in evaluating the pharmaceutical sector in relation to

[40] (HAI, 2013)

[41] (Byrne, 2010)

access to essential medicines (refer to **Appendix xxxi** for the analysis of alternative pharmaceutical benchmarking studies related to access to essential medicines). A limitation of the analysis performed was that most alternate indices only included access to essential medicines as a sub component of the larger environmental and social governance framework. The ATMi was noted to be comparatively stronger in terms of its holistic approach to assessing access to essential medicines, free availability to public, evaluation of both public and sensitive private information, transparent scoring methodology, regular frequency and engagement of external non-pharmaceutical company stakeholders in the development of the scoring methodology. However, the ATMi was noted to be comparatively weaker in terms of the disclosure by not detailing indicator level scores, with three benchmarking studies providing full scoring transparency. Greater transparency would help to bolster the credibility and accuracy of the ATMi.

Greater disclosure would facilitate more alignment with alternate third party measures of performance to enhance credibility

The ATMi needs to detail indicator level scores to enable a comparison and the validation of company performance with third party measures. For example, the ATMi findings are not consistent with the 2012 CPA-Zicklin Index of Corporate Political Accountability and Disclosure and the Center for Responsive Politics 2012 lobbying spend, despite an overlapping focus on the disclosure and governance of lobbying spend. CPA-Zicklin index notes that the most transparent pharmaceutical companies were Merck & Co, Gilead Sciences and Johnson and Johnson, while the ATMi recognized GlaxoSmithKline, Sanofi and Novo Nordisk A/S as the leaders in terms of transparency. The Center for Responsive Politics noted in 2012 that the pharmaceutical sector lobbying spend was USD 232 million in the US, with the top lobbyists being Eli Lilly & Co, Pfizer Inc, Merck & Co. and Novartis (refer to **Appendix xxxii** for the 2012 pharmaceutical industry lobbying profile).[42] The Center for Responsive Politics further notes that Pfizer's lobbying activities included a focus on intellectual property protections in the Trans-Pacific Partnership Agreement, U.S. intellectual property rights overseas; issues relating to an Indian Supreme Court decision on generic medicine pricing and issues relating to cancellation of patent in India and medicines

[42] (Opensecrets, 2013)

in Turkey.[43] Additional lobbying activities noted included Merck on the Trans-Pacific Partnership Agreement and biologic data exclusivity, Eli Lilly & Co on international property protection and international market access issues and Novartis A/G on free trade agreements related to intellectual property provisions in Panama, Colombia, Korea Access, the Trans-Pacific Partnership, global influenza pandemic and substandard medicine quality.[44] The ATMi noted the best performers in terms of public policy as Sanofi, Bristol-Myers Squib Co and Novartis, with Eli Lilly & Co equally placed with other companies including Merck & Co. for third, and narrowly above Pfizer.

Disaggregated indicator ratings are necessary for stakeholders to analyze and validate findings from different vantage points of accountability

ATMi ratings should be disaggregated to the indicator level to enable different stakeholders to evaluate and validate absolute performance level against alternative perspectives of industry accountability. The ATMi publicly disaggregates rankings only to the strategic and technical area level, limiting the ability of different stakeholders to understand and validate absolute performance levels. The ATMf does share with pharmaceutical companies their absolute scores for select indicators upon request. An analysis of changes in the rating of each company between 2010 and 2012 could not always be explained by individual company activities as reported by ATMi; an inherent limitation of focusing on relative performance where rating changes can be attributed to competitor actions (refer to **Appendix xxx** for the analysis of changes in company performance from 2010 to 2012). The Aid Transparency Index is a good representative model of transparency, publishing not only its results by organization and indicator, but also the evidence used, comments on evidence and outcomes of the peer review. The University Global Health Impact Report Card is another good model of disaggregated reporting. Disaggregated indicator information should be supported by evidence gathered, when not subject to confidentiality restrictions.

Lack of absolute performance transparency can erode the perceived credibility of the ATMi by not allowing independent validation (refer to **Appendix xxxiii, xxxiv and xxxv** for an

[43] (Opensecrets, 2013)

[44] (Opensecrets, 2013)

independent analysis of Gilead Sciences, Sanofi and Novo Nordisk product portfolio and research pipeline). The ATMi does not facilitate an analysis by product of each company's relevant patent policies, registration, tiered pricing, non-exclusive voluntary licenses, sales and donations segmented by country, which can result in skewed reporting. For example, the ATMi only acknowledged the positive contributions by Gilead for Viread and Truvada in terms of HIV/AIDS drugs, not referencing three other relevant drugs, Atripla, Emtriva and Stribild, one of which Gilead was also making more accessible. As a result, the ATMi fails to draw attention to activities related to medicines on the WHO EML that fall outside of the index disease scope but are still important to monitor, such as Gilead's Tamiflu (influenza), Sanofi's wide range of vaccines and Taxoterne (oncology) and Novo Nordisk's NovoSeven (hemophilia). The ATMi also does not facilitate a reconciliation of each company's product portfolio and research pipeline to the diseases in scope, which can result in reporting inconsistencies. For example, Gilead was noted as conducting research in relation to Hepatitis C, Hepatitis B, Liver Fibrosis and Type 2 Diabetes, the first three indirectly related to in-scope diseases and the last an in-scope disease, however none were acknowledged by the ATMi. Sanofi was noted as conducting research in Tetanus and Hepatitis B and had products for Lymphatic Filariasis, Trypanosomiasis and Osteoarthritis, all in-scope diseases not acknowledged by the ATMi. Additionally, Sanofi was given credit for products related to low respiratory infections, malaria, tuberculosis, pertussis, cerebroacular disease, osteoarthritis, and leishmaniasis, and research related to diarrheal diseases, tuberculosis, ischaemic heart disese, cerebrovacular disease, COPD, leishmaniasis and trypanosomiasis which was not able to be reconciled to Sanofi's product and research pipeline on their website.

iv. Greater disclosure and analytical tools would more effectively inform stakeholders

More complete and detailed disclosure of company information would make the ATMi a more trusted and complete measure of industry performance

Although the ATMi focuses on publishing positive contributions by pharmaceutical companies in order to encourage leadership by example, more detailed and complete coverage is required of activities that limit access to essential medicines. An analysis was

performed utilizing Factiva, Lexis / Nexis, ABI / Inform Complete, Business Source Complete and Global Socrates - Corporate Social Responsibility to identify key access to essential medicine issues not adequately addressed by ATMi. The ATMi was noted not to have addressed the global advocacy campaign in 12 countries to challenge Abbott Laboratories' monopolistic hold on Kaletra (lopinavir+ritonavir), considered a key part of HIV/AIDS treatment regimens.[45] An administrative judge in Colombia ruled in 2012 that Abbott improperly maintained the price of the Kaletra AIDS medication above the so-called reference price.[46] The ATMi did not note in 2012 that Abbott Laboratories had filed a citizen's petition with the Food & Drug Administration asking the agency not to approve any biosimilar for its Humira treatment for rheumatoid arthritis, which has the potential to restrict product innovations.[47] Although the ATMi did acknowledge the potential negative implications of legal cases relating to patentability criteria (Novartis) and compulsory licensing (Bayer), the Gilvec and Nexavar cases respectively were mentioned only summarily in one combined sentence, not reflective of their significance.[48] The ATMi was also noted not to have addressed the Trans-Pacific Partnership Agreement, which the pharmaceutical industry is utilizing to enforce stronger copyright, patent protection, and data exclusivity.[49]

ATMi reporting of company performance by technical area and company report cards needs to provide more depth, balance and context. The ATMi only reports on activities in the two-year period under evaluation, often providing limited contextual information and depth. Information not always detailed includes when initiatives are started and their related activities and partners, and the full product and research pipeline and related access policies. Further, the one to two page company report cards at the end of the ATMi report don't provide a balanced representation of absolute performance. For example, litigation and ethical breaches are often entirely excluded from the summary report cards, such as for instance the 2011 Securities and Exchange Commission charge of Johnson & Johnson in

[45] (Rosenberg, 2012)

[46] (Silverman, 2012b)

[47] (Silverman, 2012a)

[48] (H. V. Hogerzeil et al., 2013)

[49] (Baker, 2012)

relation to the UN Oil for Food Programme and AstraZenca's 28 marketing and sales breaches. The information communicated in the company scorecards is particularly important as they represent the only consolidated summary of absolute performance generated by the ATMi, with the information contained replicated on the ATMi website. The company report cards need to be more representative of each company's absolute performance for each technical area evaluated. The ATMi should additionally maintain a complete, time scaled repository of the activities of index companies on its website, with supporting links to more in-depth information where publicly available.

Visualization and data analysis tools would enhance ability to evaluate performance over time across different criteria

The ATMf needs to provide visualization and data analysis tools to facilitate the analysis and comparison of company performance over time. The diversity of stakeholders the ATMi is servicing necessitates the ability for information to be screened based on alternate accountability criteria. All information detailed by the ATMf is currently in a static and text form, other than graphical representations of technical and strategic level scores. There is no ability to use tools to compare information, over time, across regions or diseases. The ATMf should provide analytical and data visualization tools in a format that enhances understanding, simplifies and standardizes information and empowers greater analysis. For example, a graphical map that displays the products and initiatives of companies individually and in aggregate in different countries by disease could be helpful to compare to disease incidence over time. A tool that analyzes the research and development product pipeline across companies and highlights potential gaps in response to future disease incidence could be important in fuelling public debate. Another important contribution could be a filtering tool that allows the public to quickly analyze product portfolios to identify essential medicines and understand the related accessibility policies of companies. The Carbon Disclosure Project illustrates the potential of advanced analytics to both empower users and generate earned revenue by being able to search for information using various modifiable criteria. The Corruption Perception Index demonstrates the potential of infographics to enhance the delivery of messages and facilitate customized queries.

More frequent reporting would deliver more relevant and accurate information

The rapid developments across the pharmaceutical sector require frequent reporting to provide relevant and accurate information to users. The ATMi currently publishes an industry index every two years and does not otherwise report on developments across the industry. Index scores published every two years can quickly become obsolete. For example, the 2010 ATMi scored Johnson & Johnson positively for entering negotiations with the Medicine Patent Pool, however by December 2011 Johnson & Johnson had withdrawn from the negotiations. More frequent updates would ensure the index scoring was reflective of current practices. The ATMi should regularly report updates on its website relating to index companies to draw attention to key developments relating to access to essential medicines. For example, the ATMi could have drawn attention to the recent launch by Eli Lilly & Co of a legal challenge under the North American Free Trade Agreement demanding USD 100 million in compensation for the Canadian court decision striking a patent for an attention-deficit disorder drug.[50]

v. Additional distinct measures would enhance insight on access to essential medicines bottlenecks

Gap in access to generic drugs needs greater attention to improve access to essential medicines

A complementary and distinct measure is required to provide insight on the affordability and availability of generic drugs. The challenges of access to generic drugs are distinct from branded products and need to be accordingly reflected in a unique evaluation framework. Rather than placing a focus on generic companies, a complementary index should rank individual generic products or categories in terms of the level of competition that exists, to ensure generic drugs are available, cheap and of sufficient quality.

The ATMi commenced in 2008 by evaluating generic manufacturers and originator pharmaceutical companies under the same evaluation framework. In 2010, the ATMi evaluated originator pharmaceutical companies and generic manufactures under two different

[50] (Gray, 2012)

frameworks, however after further stakeholder consultations generic manufacturers were entirely excluded in 2012. We understand that the exclusion was attributed to the need for more specific measurement standards specific to the generic manufacturing industry, which the ATMf is exploring for potential inclusion in 2014. [51]

Generic drugs and manufacturers represent the core component of access to essential medicines. Over 90% of the medicines on the WHO EML are generic drugs currently excluded by the ATMi; one-third of the population of the developing world is unable to receive or purchase essential medicines on a regular basis.[52] Average public sector availability of generic medicines across WHO regions is 29.4%-54.4%.[53] The global generics market represented 75% of the total pharmaceutical volume in 2011 and is expected to rise to 85% by 2016.[54] The boundary between generic manufacturers and originator pharmaceutical companies is eroding over time, with Sandoz representing the generic pharmaceutical division of Novartis and Teva Pharmaceutical Industries Ltd moving into branded medicines following the purchase of Hutexil in 2013.

Contributions of distributors, biotechnology companies, and small and medium sized enterprises to access to essential medicines needs to be monitored

Distribution companies, biotechnology companies, and small and medium sized enterprises (SME) represent important industry stakeholders in increasing access to essential medicines that need to be continuously monitored (refer to **Appendix vi** for further details on the composition of the global pharmaceutical sector). Monitoring is necessary to encourage positive contributions and discourage activities that limit access to essential medicines. Rather than developing a separate index, the ATMf should focus on attracting greater attention to industry activities that positively or negatively impact access to essential medicines, by publishing industry updates on its website.

[51] (AMI, 2012a, p. 104)

[52] (WHO, 2013)

[53] (Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2008 p.1)

[54] (Marketline, 2012c p.2)

Distribution companies, biotechnology companies, and SMEs will continue to play an important role in enhancing access to essential medicines. Cumulative markups in low- and middle-income countries by wholesalers, importers and retailers can range from 17-84% in the public sector and 11%-6,894% in the private sector.[55] Global out-of-country distributors or bulk purchasers / procurement agencies currently only offer their services to vertical programs like the Global Fund, but may in the future offer their services to country supply chain managers. By 2016, the global biotechnology market is estimated to equal half the value of the global drug pharmaceutical market.[56] SMEs accounted in 2005 for half of all identified neglected disease drug projects and in 2011 for 10.6% of total industry funding in neglected diseases.[57] Further, small companies such as Royalty Pharma that acquire patent rights to biopharmaceutical products may in the future limit access to essential medicines. SMEs in developing or emerging markets are likely to play a larger role in serving the needs of access to medicines in developing countries. A leading biotechnology company and SME includes Anacor and Humax Pharmaceutical, both part of the Drugs for Neglected Diseases Initiative, and two leading global distributors include IDA and I+ Solutions.

Suboptimal government policies need greater focus to improve access to essential medicines

An additional index needs to be developed that evaluates the infrastructure, policies and distribution network of each country in terms of access to essential medicines. The 2006 Global Corruption Report on the health sector of Transparency International and the Medicines Transparency Alliance (MeTA) reflect a growing focus on governance at the country level.[58] Governance of essential medicines at the country level should include a focus on national anti-corruption efforts, medicine regulations (including discriminatory laws based on race, gender, health status, etc.), regulatory authorities, medicines registration, licensing of pharmaceutical establishments, inspection and market control, medicine

[55] (Ball, 2011 p.11 & 27)

[56] (Marketline, 2012b p.6)

[57] (M Moran et al., 2012, p. 88)

[58] (Baghdadi□Sabeti, Clare Cohen□Kohler, & Wondemagegnehu, 2009, p. 3)

promotion control, clinical trials of medicines, selection of medicines, procurement of medical products, and distribution of medicines.[59]

As different countries will have different starting points on any prescribed measures, the important measures need to include actionable indicators that go beyond pointing out obvious disparities rooted in socio-economic differences. Examples of specific measures that could motivate the reallocation of resources or greater dedication of efforts include: tariff barriers on malaria bed nets in contradiction of the Arusha Declaration commitments; successful performance on grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria; average availability of selected medicines in public and private health facilities; percentage of the population covered by health insurance; existence of legal provisions to encourage generic substitution; and taxes and duties on essential medicines.[60] This study acknowledges that certain transparency measures at the national level, such as in relation to research and development tax credits by product, may complicate efforts of securing greater collaboration from multi-national corporations for the ATMi, however overall it should contribute to enhanced access to essential medicines.

Country governance represents a significant barrier to access to essential medicines and requires greater transparency and standardization of environments. A study of 36 low- and middle-income countries noted that public and private sector facilities only had essential medicines in stock one third and two thirds of the time respectively.[61] Per 10,000 people in Brazil, India and China there are only 12, 6 and 14 doctors respectively.[62] Investment by national governments in the health-care sector, particularly across Africa, has remained low, with national budgets decreasing for general essential medicines and general health and supply systems.[63] As of 2011, 50 countries have not updated their list of essential medicines to guide public supply or reimbursement.[64] WHO estimates that in many countries up to half

[59] (Baghdadi□Sabeti et al., 2009, pp. 21-109)

[60] (WHO, 2012b)

[61] (H. Hogerzeil & Mirza, 2011 p.8)

[62] (SustainAbility, February 2009 p.16)

[63] (WHO, 2009 p.16)

[64] (H. Hogerzeil & Mirza, 2011 p.8)

of all prescriptions are either unnecessary or incorrect and that in about half of all cases patients do not take their medications as prescribed.[65]

g. Study limitations

Limited Stakeholder Participation

This study attempted to sample a range of perspectives across the pharmaceutical sector, investor groups, global health organizations and human rights organizations, however the responses received, while valuable, cannot be considered representative (refer to **Section K** for a full listing of participants). Greater public dialogue is encouraged concerning efforts to measure the performance of the pharmaceutical sector in terms of access to essential medicines.

Lack of Access to Information

The ATMi is able to evaluate a wide breadth of performance standards by obtaining access to sensitive and confidential information, however the resulting lack of transparency of activities and scores limited the ability of this study to benchmark results and findings. Greater levels of transparency across the pharmaceutical sector and the ATMi are encouraged to promote a more inclusive dialogue on the performance standards across the pharmaceutical sector.

h. Areas for further study

Importance of Avoiding the Light Under the Lamp Post Syndrome

Access to essential medicines is not only relevant to the disease, country and product scope of the ATMi, therefore care needs to be taken that the focus of the ATMi does not detract from activities in other important areas. Examples were noted of medicines on the WHO EML that fall outside of the index disease scope, such as Gilead's Tamiflu (influenza), Sanofi's wide range of vaccines and Taxoterne (oncology) and Novo Nordisk's NovoSeven (hemophilia) for which access policies are still important. Additionally, the ATMi does not include in its scope countries with high level of internal income disparities, such as Columbia

[65] (WHO, 2009 p.4)

(10th worst in world), Chile (15th), Brazil (16th), Mexico (18th) and Russia (51st).[66] The Human Development Report 2006 noted wide disparities in the HDI rankings of the richest and poorest 20% of populations through a disaggregated study of 13 developing countries.

The ATMi could limit public attention on other important aspects of promoting access to essential medicines if it was to play a more dominant role in setting the public agenda. It is understandable that the ATMi limits its scope to enable its limited resources to provide a sufficient depth of analysis. However, it is also important that pharmaceutical companies are encouraged to proactively make access to all their medicines in terms of diagnosis, treatment and prevention, particularly medicines listed on the WHO EML, available to all disadvantaged communities. Close monitoring is required to ensure that companies do not only focus on the scope of the ATMi in providing access to essential medicines and that out-of-scope activities that contribute or detract from access to essential medicines are appropriately recognized. The ATMi may consider acknowledging on its website, but not scoring, out of scope activities that contribute to access to essential medicines.

Need for Focus on Link Between Barrier, Strategy and Specific Action

Analyzing access to essential medicines globally based on the role of one actor can neglect to place a sufficient focus on the specific and unique challenges of individual drugs and regions. Global initiatives should be supplemented by in-depth case studies to maintain a focus on the key supply-chain bottlenecks. Frost & Reich promote an evaluation framework focused on architecture (organizational dimension), availability (supply component; manufacturing, forecasting, procurement, distribution and delivery), affordability (cost component; government affordability, non-governmental agency affordability and end-user affordability) and adoption (demand component; global adoption, national adoption, provider adoption and end-user adoption and appropriate use) that integrates all actors.[67] "A deeper understanding of the facilitators, barriers, and key actors involved in achieving architecture, availability, affordability, and adoption is necessary for better access planning."[68] Case studies need to

[66] (CIA, 2013)

[67] (Frost & Reich, 2008, p. 16)

[68] (Frost & Reich, 2008, p. 18)

support the ATMi in-scope disease focus to ensure that global attention is being placed on the key barriers that will most significantly improve access to essential medicines.

Greater Emphasis Required on Outcomes

More case studies are required to demonstrate alternative approaches to measuring outcomes objectively. The pharmaceutical sector depends more on outputs in terms of the number of drugs delivered, number of countries reached and value of donations as examples to demonstrate impact. Impact needs to focus on measuring the ability of disadvantaged communities to have access to, afford and rationally use essential medicines. Collaborative studies as part of public-private partnerships should be considered to evaluate the impact of pharmaceutical initiatives on the lives of the disadvantaged. Case studies measuring impact add to the credibility of activities by the pharmaceutical sector and center attention on the people that do not have adequate access to essential medicines.

Need for Standardized and Public Measures of Pharmaceutical Company Performance

A comprehensive and standardized reporting framework is required for the pharmaceutical sector to enhance transparency and reduce the reporting burden regarding social, environmental and governance activities, particularly in relation to access to essential medicines. The Global Reporting Initiative (GRI) provides general corporate responsibility guidelines that have been adopted by a number of pharmaceutical companies including Novartis, Johnson & Johnson, Pfizer and Bayer. However, GRI does not provide pharmaceutical sector-specific guidelines, an initiative advocated for by Novartis.[69] A study should be conducted to identify the reporting framework and terms and definitions that optimally balance the information needs of different stakeholder groups. Greater standardization of information reported by the pharmaceutical sector would enhance the ability to benchmark performance and reduce the reporting burden to such transparency initiatives as the ATMi.

[69] (Pharmaceutical Shareowners Group, 2004, p. 20)

Challenge of Identifying Optimal Versus Actual Contribution

In determining the optimal level of contributions of companies, a greater understanding is required of the value offerings of each company. In 2005, five of the top 12 multinational pharmaceutical companies did not conduct neglected disease drug research and development, and in 2012 this represented half of all companies in the ATMi based on the in-scope neglected tropical diseases.[70] In 2005, the multinational companies that left the neglected disease field made it clear that commercial incentives or good public relations would not be sufficient to change their neglected disease focus.[71] This can be attributed to companies focusing on a small number of commercially rewarding therapeutic areas and cutting lose non-core disease areas including infections diseases and veterinary divisions.[72] Further study is required on ways to identify the value each company can optimally contribute in terms of knowledge, expertise and resources in comparison to actual performance. As an example, the commitment by Gilead Sciences to donate 455,000 vials of AmBisome during 2012-2017 to treat 50,000 people, could be weighed in context of its USD 8 non-profit value and the fact that 12 million people world-wide are affected by visceral leishmaniasis.[73]

Analyzing the Value of a Proactive Response to Access to Essential Medicines

A focus needs to be made on measuring the commercial benefits to companies of proactively responding to the challenge of access to essential medicines. In 2004, the Pharmaceutical Shareowners Group, an international grouping of 14 institutional investors with significant exposure to the pharmaceutical sector, noted a number of risks stemming from the public health crises in emerging markets on the long-term shareholder value of the pharmaceutical sector.[74] Attempts should be made to objectively measure benefits arising from proactive access to essential medicines approaches in terms of the preservation of suitable intellectual property laws and patent treaties, protection of company reputation and license to operate,

[70] (Mary Moran et al., September 2005, p. 15)

[71] (Mary Moran et al., September 2005, p. 15)

[72] (Mary Moran et al., September 2005, p. 15)

[73] (Gilead, 2013)

[74] (Pharmaceutical Shareowners Group, 2004, p. 3)

political goodwill to secure future markets, improved stakeholder relations and enhanced employee morale and recruitment prospects.[75]

Completeness of Essential Medicines List

The WHO EML has been used as the primary basis for identifying drugs that pharmaceutical companies should be making more accessible to disadvantaged communities. Continued studies are necessary to ensure that the optimal and best in class medicines to diagnose, prevent and treat key diseases are included in the WHO EML. Oncology represents one area of continued concern in terms of high prices based on interviews and surveys conducted.

i. Conclusion

Actionable governance indicators (AGI) represent important mechanisms in promoting industry sector change. The success of AGIs is dependent on their capacity to maximize the transparency of practices and empower multi-stakeholder collaboration and dialogue. The ATMi is a recently developed AGI that has in six years helped to shape certain industry practices in relation to access to essential medicines. The ATMf has established a new precedent for objectively evaluating access to essential medicines across the pharmaceutical sector by accessing sensitive information and engaging in an open dialogue with diverse stakeholders.

The ATMi needs to continue to build on its achievements in order to promote further meaningful change across the pharmaceutical sector. A key challenge for the index will be to enhance its engagement with different stakeholder groups in order for pharmaceutical companies to perceive greater benefits to costs in improving their performance.

This paper identifies a number of opportunities for the ATMf to enhance its engagement with its diverse stakeholders. If the ATMf fully adopts the values it desires to encourage across the pharmaceutical sector, by being more objective, transparent, accountable and collaborative, it should continue to comprise an important lever in promoting positive industry change.

[75] (Pharmaceutical Shareowners Group, 2004, p. 3)

j. Appendix

i. Factors limiting access to essential medicines

- *High cost:* Spending on pharmaceuticals as a proportion of total public and private health for developed, transitional and developing economies is 20%, 15-30% and 25-66% respectively.[76] Across 33 countries, the lowest-priced generic medicines in the private sector were observed to be more than double the prices in the public sector, with price differentials being greater for branded products.[77]

- *Inefficient distribution:* Medicine prices consist of manufacturer costs, duties, taxes and markups. Cumulative markups in low- and middle-income countries by wholesalers, importers and retailers can range from 17-84% in the public sector and 11%-6,894% in the private sector, though in many countries the manufacturer's selling price is the major contributor to the final price.[78] In low- and middle-income countries private sector patients paid 9-25 times international reference prices for lowest-priced generic products and over 20 times international reference prices for originator products.[79] A 2003 study by BUKO of over 2,500 drugs exported by Germany to forty-six countries noted that 39% were irrational (i.e. ineffective or damaging) and that significantly more time was required to remove drugs from developing countries in response to safety concerns as compared to Germany.[80]

- *Limited health infrastructure:* A study of 36 low- and middle-income countries noted that public and private sector facilities only had essential medicines in stock one third and two thirds of the time respectively.[81] Average public sector availability of generic medicines

[76] (WHO, 2012a)

[77] (WHO, 2009 p.4)

[78] (Ball, 2011 p.11 & 27)

[79] (Cameron et al., 2008 p.1)

[80] (Forman & Kohler, 2012 p.127)

[81] (H. Hogerzeil & Mirza, 2011 p.8)

across WHO regions is 29.4%-54.4%.[82] Per 10,000 people in Brazil, India and China there are only 12, 6 and 14 doctors respectively.[83]

- *Limited health financing*: Investment by national governments in the health-care sector, particularly across Africa, has remained low, with national budgets decreasing for general essential medicines and general health and supply systems.[84]

- *Narrow disease focus*: The selective approach of focusing on priority diseases is resulting in the neglect of other important developing country conditions such as chronic diseases and common diseases in children.[85] In low- and lower-middle income countries, drugs for chronic conditions were 33.9% and 12.9% less available in the public sector than medicines for acute conditions, with a narrower gap observed in the private sector.[86]

- *Inequitable health financing mechanisms*: Up to 90% of households in developing countries with relatively limited purchasing power are responsible for the cost of essential medicines.[87] In low-income countries without effective public healthcare systems, medicines can account for 50-90% of household out of pocket expenditure on health.[88] A survey across 16 low- and middle-income countries noted that 86% of the population would be pushed into poverty by purchasing one of four medicines based on median patient prices.[89]

- *Limited R&D pipeline*: Approximately 10% of the global pharmaceutical research and development expenditure goes towards diseases that account for 90% of the world's disease burden.[90] In 2010 $3.1 billion research and development was reported for Type II and Type III neglected diseases, reflecting a 3.5% fall from 2009 and representing 4.6%

[82] (Cameron et al., 2008 p.1)

[83] (SustainAbility, February 2009 p.16)

[84] (WHO, 2009 p.16)

[85] (WHO, 2009 p.16)

[86] (Cameron A et al., 2011 p.393-468)

[87] (DFID, 2005 p.18)

[88] (DFID, 2005 p.18)

[89] (Niëns et al., 2010)

[90] (Bluestone, Heaton, & Lewis, 2002 p.8)

of the total global R&D spend of $67.4 billion in 2010.[91] [92] Cumulative funding for HIV/AIDS, TB and Malaria in 2010 represented 71.7% of all Type II and Type III infectious disease funding.[93]

- *Lack of data and coordination:* Information systems supporting medical supply chains are weak, making performance monitoring and efficiency evaluations challenging.[94] The many different partners with their specific medicines supply strategy has limited global coordination, resulting in duplication and inefficiency.[95] As of 2011, 50 countries have not updated their list of essential medicines to guide public supply or reimbursement.[96]

- *Limited quality controls:* In August 2012 China detained approximately 2,000 people and seized $182 million in fake medicine, including fraudulent drugs for the treatment of cancer, hypertension and diabetes.[97] A meta-analysis of anti-malarial drug studies in seven countries in South East Asia noted 35% failed chemical analysis, 46% failed packaging analysis and 36% were classified as falsified, with the respective findings for 21 sub-Saharan Africa countries being 35%, 36% and 20%.[98] A 2005 study of the top 25 selling brands of medicines in India noted that ten were irrational, non-essential or hazardous.[99]

- *Ineffective practices:* WHO estimates that in many countries up to half of all prescriptions are either unnecessary or incorrect and that in about half of all cases patients do not take their medications as prescribed.[100]

[91] (PhRMA, 2011 p.2)

[92] (M Moran et al., 2011 p.9)

[93] (M Moran et al., 2011 p.9)

[94] (WHO, 2009 p.16)

[95] (WHO, 2009 p.16)

[96] (H. Hogerzeil & Mirza, 2011 p.8)

[97] (Barboza, 2012)

[98] (Nayyar, Breman, Newton, & Herrington, 2012)

[99] (Forman & Kohler, 2012 p.127)

[100] (WHO, 2009 p.4)

ii. Definition of Type I, II and III diseases

"Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and Haemophilus influenzae type b (Hib), and examples of noncommunicable diseases abound (e.g., diabetes, cardiovascular diseases, and tobacco-related illnesses). In the case of Type I diseases, the incentives for R&D exist in the rich country markets…Products get developed, and the main policy issue, visà-vis the poor countries, is access to those technologies, which tend to be high priced and under patent protection…Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. R&D incentives exist in the rich country markets, therefore, but the level of R&D spending on a global basis is not commensurate with disease burden. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries. In the case of vaccines for HIV/AIDS, substantial R&D is underway as a result of rich country market demand, but not in proportion to global need or addressed to the specific disease conditions of the poor countries. In the case of TB the situation is even worse, with very little R&D underway for new and better treatment. Type III diseases are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans."[101]

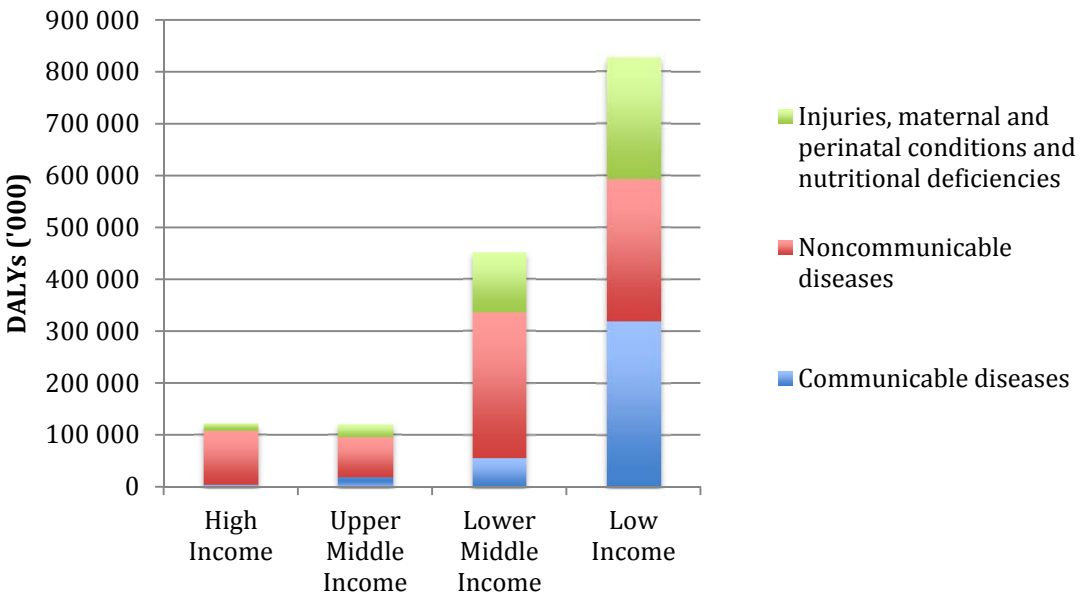
[101] (Sachs, 2001 p.78)

iii. Analysis of global burden of disease statistics

An analysis of the World Health Organization (WHO) global burden of disease statistics published in 2004 and updated in 2008 indicates 1.13 billion DALYs were lost due to communicable and non-communicable diseases. 82.1% of the total global disease burden was attributed to low-middle and low-income countries that represent 75.8% of the world's population.

Non-communicable diseases represent the predominate cause of DALYs lost globally, however communicable diseases represent the largest DALY impact in low-income countries. If the population age distribution were controlled for, non-communicable disease risks would be higher in low- and middle- income countries than in high-income countries.[102] Children less than 15 years of age were attributed to half of the disease burden in low-income countries, despite representing only 37% of the population.[103]

Figure 2: 2004 (Updated 2008) Global Burden of Disease



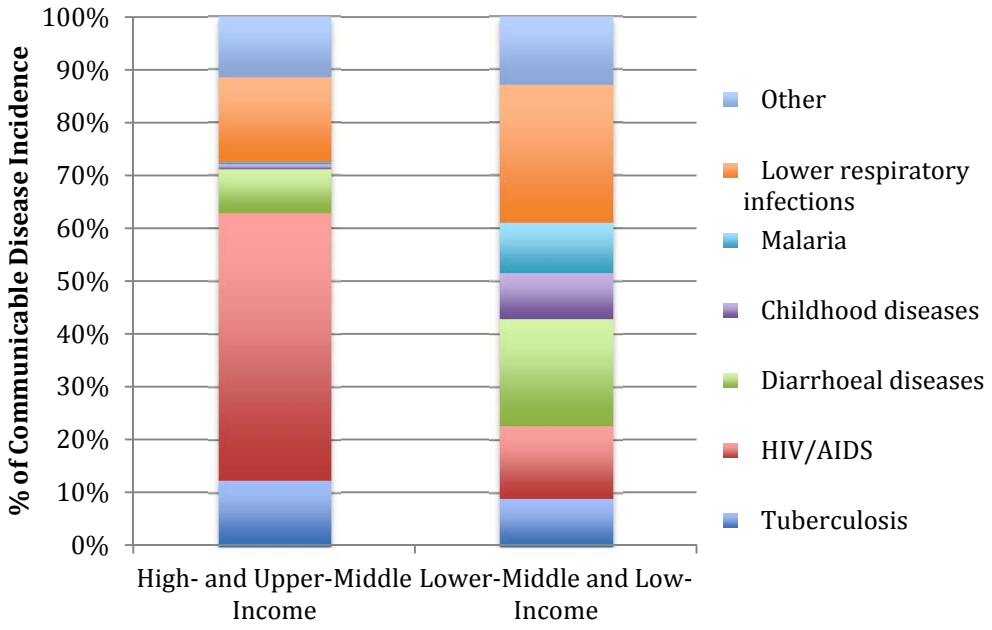
Source data: WHO 2004 (updated 2008) Summary: DALYs (000s) by cause and income group

[102] (WHO, 2008 p.48)

[103] (WHO, 2008 p.42)

An analysis of the non-communicable diseases reveals similar incidence rates across low-, lower-middle-, upper-middle-, and high-income countries, with the five largest disease burdens represented by neuropsychiatric disorders, cardiovascular disease, sense organ disorders, malignant neoplasms and respiratory diseases (refer to **Appendix v** for the disease incidence rates). An analysis of communicable diseases reveals that over 85% of the burden in high- and upper-middle income countries can be attributed to HIV/AIDS, lower respiratory infections, tuberculosis and diarrheal diseases. In lower-middle income and low-income countries 85% of the communicable disease burden can be attributed to lower respiratory infections, diarrheal disease, HIV/AIDS, malaria, tuberculosis and childhood diseases. Communicable disease burden represents a significant unfinished agenda in low-income countries (even compared to lower-middle-income countries).

Figure 3: 2004 (Updated 2008) Communicable Disease Incidence by Income



Source data: WHO 2004 (updated 2008) Summary: DALYs (000s) by cause and income group

In 2030, global DALYs are predicted to decrease by approximately 10% due to assumed increases in overall living standards.[104] It is projected that non-communicable diseases will

[104] (WHO, 2008 p.49)

represent 66% of the total DALY's lost.[105] The three leading causes of DALY's globally are anticipated to be unipolar depressive disorders, ischaemic heart disease and road traffic accidents.[106]

[105] (WHO, 2008 p.50)

[106] (WHO, 2008 p.50)

iv. International human rights legal framework

The international legal framework surrounding the right to health continues to evolve at the state level through progressive accountability measures. Article 25(1) of the Universal Declaration of Human Rights of 1948 recognizes the right to medical care and medicines in promoting health and well-being. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1976 recognizes the right to enjoy the highest attainable standard of physical and mental health. In 2000 the Committee on Economic, Social and Cultural Rights (CESCR) issued General Comment 14 that requires states to take deliberate steps towards the full realization of the right to health, including the provision of essential drugs and immunizations.

The challenge however remains in applying universal human right ideals in light of diverse cultural values and limited state resources.[107] Over 30 countries have not ratified ICESCR and 60 countries do not recognize the right to health in their national constitution.[108]

> "…many governments, including that of the United States do little to redress inequalities in health, while others are largely powerless to address such inequity. The reasons for failure are many and varied, but even optimists allow that human rights charters and covenants have not brought an end to – and may not even have slowed – egregious abuses, however they are defined."[109]

CESCR General Comment 14 notes that the private business sector has responsibilities regarding the realization of the right to health. In 2003, the UN Sub-Commission on the Promotion of Human Rights approved a set of norms on the responsibilities of transnational corporations that included contributing to the realization of rights to the highest attainable standard of physical and mental health. In 2011 the UN Human Rights Council endorsed the Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect, and Remedy" framework that specified: the state obligation to protect against corporate-related human rights abuse, the corporate responsibility to respect human rights, and access to effective remedy.

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[107] Wolff (2012 p.25)

[108] (H. Hogerzeil & Mirza, 2011 p.1)

[109] Farmer (2003 p.222)

The Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines of 2008 promulgated by the United Nations Human Rights Council provide sector specific guidance in promoting access to medicine.[110] The guidelines require pharmaceutical companies to recognize the right to the highest attainable standard of health, particularly of the disadvantaged. The recommendations included, but were not limited to, transparent reporting, standardized disclosure, independent monitoring and accountability mechanisms, ethical practices and an increased focus on research and development for neglected diseases.

In 2009, the Special Rapporteur on the right to health visited the headquarters of GSK, a company regarded as one of the leading exponents of corporate social responsibility in the pharmaceutical sector.[111] The Special Rapporteur made clear in his report that pharmaceutical companies have right-to-health responsibilities that exceed the ethical and legal requirements implicit in shareholder primacy, a position that GSK rejected.[112] This paper acknowledges the leading role of Andrew Witty, Chief Executive Officer, GSK in supporting global access to medicines and in lowering the costs of research and development to bridge the gulf in bringing needed treatments to market.

> "A member of the senior management of an innovator pharmaceutical company recently remarked…that the company's patents were "its crown jewels". The image was revealing. In one sense, the image is legitimate - patents are immensely valuable. In another sense, the image reflects a profound misunderstanding of the role of a company that develops a life-saving medicine…such a company has performed a critically important social, medical, public health and right-to-health function. While the company's "reward" is the grant of a limited monopoly over the medicine, enabling it to enhance shareholder value and invest in further research and development, the company also has a right-to-health responsibility to take all reasonable steps to make the life-saving medicine as accessible as possible, as soon as possible, to all those in need. For a limited period, the company holds the patent for society - but the patent must be worked, so far as possible, for the benefit of all those who need it."[113]

[110] (Hunt, 2008)

[111] (Hunt, 2009 p.5)

[112] (Forman & Kohler, 2012 p.77)

[113] (Hunt, 2009 p.25)

v. DALYs ('000s) by cause and income group (3% discounting, Age weights)

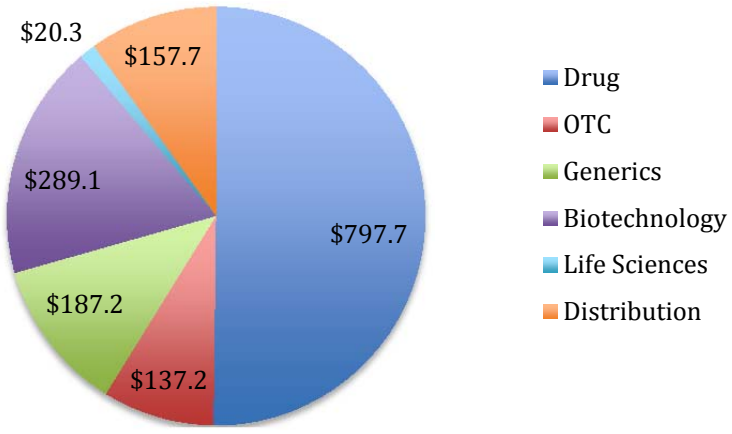
Cause	WORLD		HIGH INCOME		UPPER MIDDLE INCOME		LOWER MIDDLE INCOME		LOW INCOME	
Population (000)	*6 436 826*		*977 189*		*579 621*		*2 464 976*		*2 412 669*	
	(000)	*% total*	*(000)*	*% total*	*(000)*	*% total*	*(000)*	*% total*	*(000)*	*% total*
DALY Incidence % Per Population		24%		12%		21%		18%		34%
TOTAL DALYs	**1 523 259**	**100.0**	**122 092**	**100.0**	**121 032**	**100.0**	**451 827**	**100.0**	**827 669**	**100.0**
I. Communicable diseases	**399 930**	**26%**	**4 128**	**3%**	**18 649**	**15%**	**57 044**	**13%**	**319 906**	**39%**
Infectious and parasitic diseases	302 144	76%	2 754	67%	16 272	87%	41 856	73%	241 099	75%
Respiratory infections	97 786	24%	1 374	33%	2 377	13%	15 188	27%	78 807	25%
II. Noncommunicable conditions	**731 652**	**48%**	**103 529**	**85%**	**76 213**	**63%**	**278 983**	**62%**	**272 632**	**33%**
Malignant neoplasms	77 812	11%	17 826	17%	8 589	11%	32 386	12%	18 982	7%
Other neoplasms	1 953	0%	366	0%	198	0%	667	0%	721	0%
Diabetes mellitus	19 705	3%	3 623	3%	2 520	3%	7 560	3%	5 991	2%
Nutritional/endocrine disorders	10 446	1%	1 927	2%	929	1%	3 831	1%	3 753	1%
Neuropsychiatric disorders	199 280	27%	31 558	30%	19 613	26%	75 209	27%	72 824	27%
Sense organ disorders	86 883	12%	9 235	9%	6 022	8%	35 582	13%	36 010	13%
Cardiovascular diseases	151 377	21%	17 853	17%	21 399	28%	54 805	20%	57 258	21%
Respiratory diseases	59 039	8%	7 266	7%	4 174	5%	24 871	9%	22 706	8%
Digestive diseases	42 498	6%	4 714	5%	4 872	6%	14 387	5%	18 508	7%
Diseases of the genitourinary system	14 754	2%	1 248	1%	1 189	2%	5 818	2%	6 491	2%
Skin diseases	3 879	1%	230	0%	390	1%	1 419	1%	1 838	1%
Musculoskeletal diseases	30 869	4%	5 237	5%	3 409	4%	12 879	5%	9 332	3%
Congenital abnormalities	25 280	3%	1 606	2%	2 018	3%	6 512	2%	15 134	6%
Oral diseases	7 875	1%	840	1%	889	1%	3 057	1%	3 085	1%
III. Injuries, maternal and perinatal	**391 677**	**26%**	**14 434**	**12%**	**26 170**	**22%**	**115 801**	**26%**	**235 131**	**28%**
Unintentional injuries	138 564	35%	7 595	53%	12 677	67%	53 228	75%	65 015	75%
Intentional injuries	49 050	13%	3 627	25%	6 227	33%	17 960	25%	21 211	25%
Maternal conditions	38 936	10%	667	5%	1 277	5%	7 950	8%	29 022	6%
Perinatal conditions (e)	126 423	32%	1 770	12%	3 890	15%	27 401	27%	93 331	20%
Nutritional deficiencies	38 703	10%	775	5%	2 099	8%	9 263	9%	26 553	6%

Source data: WHO 2004 (updated 2008) Summary: DALYs (000s) by cause and income group

vi. Analysis of pharmaceutical industry and segments

The global pharmaceutical industry in 2010/11 was valued at $1,589.2 billion and can be segmented across drug pharmaceuticals, over-the-counter (OTC) pharmaceuticals, generics, biotechnology, life sciences tools and services and distribution. Drug pharmaceuticals include in-patient and outpatient ethical drugs. OTC pharmaceuticals include traditional medicines, vitamins, analgesics and topical products. Generics include branded and unbranded copies of off-patent ethical prescription drugs, excluding off-patent drugs offered by original manufacturers under the original name. Biotechnology includes medical/healthcare, service provider, food & agriculture, technology service, and environment and industrial processing. Life sciences tools and services include clinical and non-clinical contract research services servicing pharmaceutical and biotechnology companies. Distribution includes pharmaceutical and medical supplies. For the purposes of this paper OTC pharmaceuticals, life sciences tools and services and distribution will not be further considered as they are not directly related to the provision of essential medicines by pharmaceutical companies.

Figure 4: Global Pharmaceutical Industry Value 2010/11 ($'billion)



Source data: Marketline 2012 - Note: Distribution and OTC represent 2010 market values while remaining segments represent 2011 market values.

The overall pharmaceutical industry can be summarized as being in a consolidation phase. In 2011, 504 merger and acquisition deals took place to the value of $90 billion.[114] The merger activity has been accompanied by significant reductions in staff; since 2007 Pfizer, Merck and AstraZeneca have reduced their workforce by over 20,000 and Bayer, J&J and GSK by over 10,000.[115] The challenges associated with the expiration of valuable patents have been compounded by lower drug approval rates of new molecular entities and biologics and lower financial returns for each new drug developed associated with less drug blockbusters being identified.[116] Increasingly, in-house commercial R&D is moving to a modular R&D approach with intellectual property being directly licensed or acquired from candidate-rich but cash-poor biotechs, small companies and academics.[117] Non-core R&D activities continue to be outsourced to contract research organizations (CRO), particularly in India and China.[118] Emerging economies continue to develop as market opportunities, with global market share expected to increase from 12% to 28% by 2015, although demand will predominantly be for generic products.[119]

The global drug pharmaceutical market experienced 5.6% compound annual growth between 2006-2010 and is forecast to increase in value by 33.8% to reach $981.0 billion by 2015.[120] America, Europe, Asia-Pacific and Middle East & Africa account respectively for 44.6%, 29.2%, 25% and 1.3% of the global market value.[121] Market share is fragmented with Pfizer, Merck & Co. Inc, AstraZenca PLC and GlaxoSmithKline PLC representing the largest four companies with 9.4%, 5.3%, 4.6% and 3% of the global drug market.[122]

[114] (IMAP, 2012 p.3)

[115] (IMAP, 2012 p.6)

[116] (WHO, 2012c p.27)

[117] (Mary Moran et al., September 2005 p.9)

[118] (Mary Moran et al., September 2005 p.9)

[119] (WHO, 2012c p.29)

[120] (Marketline, 2012a p.2)

[121] (Marketline, 2012a p.8)

[122] (Marketline, 2012a p.9)

The global generics market experienced 9.1% compound annual growth between 2007-2011 and is forecast to increase in value by 46.1% to reach $273.6 billion by 2016.[123] The global generics market represented 75% of the total pharmaceutical volume in 2011 and is expected to rise to 85.1% in 2016.[124] America, Asia-Pacific, Europe, and Middle East & Africa account respectively for 46%, 29.9%, 21.8% and 2.2% of the global generics market.[125] The four largest generic manufacturers by sales are Teva Pharmaceutical, Mylan, Sandoz and Watson Pharmaceuticals, accounting for 50% of generic prescriptions in the US and 40% worldwide.[126] [127]

The global biotechnology market experienced a 9.9% compound annual growth between 2007-2011 and is forecast to increase in value by 60.9% to reach $453.3 billion by 2016.[128] The medical/healthcare sub-segment comprised 67.4% of the global biotechnology market in 2011.[129] America, Europe, Asia-Pacific and Middle East & Africa account respectively for 45%, 27.7%, 24.8% and 2.4% of the global biotechnology market.[130]

[123] (Marketline, 2012c p.7)

[124] (Marketline, 2012c p.2)

[125] (Marketline, 2012c p.10)

[126] (FiercePharma, 2010)

[127] (Harding, 2010 p.2)

[128] (Marketline, 2012b p.6)

[129] (Marketline, 2012b p.8)

[130] (Marketline, 2012b p.9)

vii. Changes in pharmaceutical practices in providing access to medicine

Enhancing access to medicines in developing countries is not only motivated by human right responsibilities; developing markets can provide transnational corporations with long term profitable opportunities to access a large population with increasing wealth. However, market incentives alone have not been sufficient to date to attract the level of investment required by the private sector.

The HIV/AIDS epidemic was pivotal in changing the practices of pharmaceutical companies in providing access to medicine. A landmark lawsuit by 39 pharmaceutical companies against the South African government was intended to prevent the passing of the 'Medicines Act,' legislation designed to gain access to affordable medicines.[131] In 2000 the US withdrew and in April 2001 the lawsuit was fully withdrawn in response to significant public pressure in the form of international petitions and demonstrations. The lawsuit was denounced as an effort by pharmaceutical companies to prevent cheaper medicines from being made available to patients and created a new norm for the protection of patents affecting health.[132] [133] In June 2001, the US similarly withdrew its WTO complaint with Brazil over patent law provisions that pressured patent holders to manufacture in Brazil in an effort to increase access to HIV/AIDS drugs.[134]

> "[AIDS] has helped catalyze the modern health and human rights movement, which leads far beyond AIDS, for it considers that promoting and protecting health and promoting and protecting human rights are inextricably connected." [135]

Public opprobrium was exacerbated by the World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS was largely shaped by the International Property Committee, an industry coalition comprised of a number of pharmaceutical companies.[136] TRIPS was adopted in 1994 and extended patent protection to

[131] (Helfer & Austin, 2011 p.146)

[132] (Pharmaceutical Shareowners Group, 2004 p.8)

[133] (Helfer & Austin, 2011 p.147)

[134] (*WTO, 2001*)

[135] (Mann & Tarantola, 1998 p.8)

[136] (Drahos & Braithwaite, 2002, p. 73)

both pharmaceutical products and processes for a period of twenty years across all WTO members, regardless of the potential negative impact on drug accessibility.[137] TRIPS did permit governments to issue compulsory licenses to use a patented product or process without an owner's consent, subject to adequate remuneration and other restrictions, including a domestic use requirement.[138] In 2001, the WTO Doha Declaration affirmed the right of WTO members to protect public health and promote access to medicines by deferring TRIPS obligations to pharmaceutical products to 2016 and affirming the right to issue compulsory licenses in national health emergencies.[139] The TRIPS Council further agreed in 2003 to waive the domestic use requirement for compulsory licensing subject to complex procedures and notification rules.[140] However, the domestic use provision has rarely been waived due to its complexity; since adoption the notable exception has been Apotex for the treatment of 21,000 HIV patients in Rwanda. Apotex has since stated that it "…is not likely to repeat the process…no second country has made a request under the regime because it's so complicated."[141]

"TRIPS Plus" treaties subsequently negotiated by the United States and European Union with many developing countries as part of bilateral and regional trade pacts have served to impose more stringent intellectual property protection standards than TRIPS, strengthening the position of foreign pharmaceutical companies and limiting the introduction of generic pharmaceutical products.[142] Since 2008 European Union customs authorities have on over twenty occasions seized and held shipments of generic medicines from India in transit to developing nations for up to eight months on suspicion of counterfeit products.[143] In 2013, the pharmaceutical industry and Interpol established the Interpol Pharmaceutical Crime Programme to focus on the prevention of all types of "pharmaceutical crime," including branded and generic drug counterfeiting, however the Indian Pharmaceutical Alliance has

[137] (Helfer & Austin, 2011 p.120-121)

[138] (Helfer & Austin, 2011 p.122-123)

[139] (Helfer & Austin, 2011 p.123)

[140] (Helfer & Austin, 2011 p.123)

[141] (Law, 2011)

[142] (Helfer & Austin, 2011 p.40 & 125)

[143] (Helfer & Austin, 2011 p.138)

expressed concerns that the Interpol agreement represents "…a continuation of the efforts by branded companies to use such agencies as Customs and universal postal unions to target generics as counterfeits."[144]

Certain developing countries have used compulsory licensing successfully. Since 2006 Thailand has successfully issued compulsory licenses for Merck's first line treatment for AIDS Efavirenz, Abbott's AIDS drug Kaletra and Bristol Myers' anti-platelet drug Plavix.[145] In 2008 Thailand issued compulsory licenses for three cancer drugs (having revoked a license for Glivec after Novartis agreed to provide its drug at no cost subject to certain income requirements) despite American pharmaceutical company lobbying for Thailand to be given Priority Foreign Country status, the most severe trade category and most likely to result in trade sanctions.[146] Since 2001, Brazil has successfully used the threat of issuing compulsory licenses to reduce the price of Merck's Stocrin, an HIV/AIDS medication, Roche's Viracept, an AIDS-fighting drug and Merck's ARV Kaletra.[147] In 2007, Brazil issued a compulsory license for Merck's Efavirenz after failing to negotiate a suitable price reduction.[148]

Responses by the pharmaceutical sector have not been systematic; pharmaceutical companies have pursued different approaches in support of access to essential medicines. The primary mechanisms pursued by the pharmaceutical sector for enhancing access to essential are detailed below and are accompanied by illustrative examples:

- *Investment in neglected disease research:* Only 13 new neglected disease drugs were developed between 1975 and 1999, yet by the end of 2004 over 60 neglected disease drug projects were in progress.[149] In 2010, the pharmaceutical industry contributed 16.5% ($503.5 million) of all research and development funding for Type II and Type III

[144] (Saez, 2013)

[145] (Helfer & Austin, 2011 p.127-128)

[146] (Helfer & Austin, 2011 p.128-129)

[147] (Helfer & Austin, 2011 p.131-132)

[148] (Helfer & Austin, 2011 p.132)

[149] (Mary Moran et al., September 2005 p.7)

infectious diseases, with the philanthropic sector contributing 18.5% ($568.1 million) and the public sector contributing 65% ($2 billion).[150]

- *Developing country investment:* Pharmaceutical companies have established a number of research centers dedicated to neglected infectious diseases. The Novartis Institute for Tropical Diseases was established in 2002 as a partnership between Novartis and the Singapore Economic Development Board to find new medicines to treat neglected infectious diseases. Novartis additionally acquired and dedicated in 2006 the Novartis Vaccines Institute for Global Health to the discovery of vaccines for neglected infectious diseases. In 2003, AstraZeneca opened a research facility in Bangalore focused on TB. In 2004, Pfizer contributed to the establishment of the Infectious Disease Institute in Uganda as a major medical training and research center. In 2010, GSK established the Tres Cantos Open Lab with seed funding of PND 5 million, providing first-class facilities, leading experts, mentors and limited financial funding to scientists focused on diseases of developing countries.

- *Collaborative product development:* The pharmaceutical industry has played an increased role in supporting joint public private initiatives (JPPIs) to target specific diseases in developing countries. The International AIDS Vaccine Initiative was founded in 1996, representing a partnership across 25 countries to research, design and develop AIDS vaccine candidates. In 1999 the Medicines for Malaria Venture (MMV) was established as a product development partnership model consisting of a network of more than 170 pharmaceutical, academic and endemic-country partners in over 40 countries focused on anti-malarial research. The TB Alliance was launched in 2000 as a product development partnership to support Tuberculosis (TB) research. The GAVI alliance was also established in 2000 to fund vaccines for children in the world's 70 poorest countries. Other public-private initiatives include, but are not limited to, the International Partnership for Microbicides (IPM), Malaria Vaccine Initiative (MVI), Foundation for Innovative New Diagnostics (FIND) and Drugs for Neglected Diseases Initiative (DNDi).

[150] (M Moran et al., 2011 p.9)

- *Improving health care delivery system:* The Roll Back Malaria initiative commenced in 1998 and includes over 500 partners supporting the scale up and coordination of malaria-control efforts at the country level. In 2002, the Global Fund was established as a partnership between governments, civil society, the private sector and affected communities to finance country specific interventions to prevent and treat HIV/AIDS, TB and Malaria.

- *Differential pricing:* Pharmaceutical companies had been negotiating drug-by-drug and country-by-country agreements with a particular focus on HIV/AIDS, though the trend is progressing towards wider reaching initiatives and diseases. The Accelerating Access Initiative (AAI) was established in 2000 and included several pharmaceutical companies that provided antiretroviral medicines at cheaper prices in developing countries and expanded related manufacturing capacity by granting voluntary licenses or non-assert declarations, contract manufacturing with generic manufacturers and technology transfer agreements. The AAI was superseded by the rapid development of generic manufacturers and other negotiated arrangements such as by the Clinton Health Access Initiative, Global Alliance for Vaccines and Immunization, Global Fund to Fight AIDS, TB, and Malaria, and the President's Emergency Plan for AIDS Relief (PEPFAR). More recently, pharmaceutical companies have begun expanding differential prices to a wider range of products. In 2009, GSK committed to cutting the prices for all drugs in 50 least developed countries to at least 25% of prices in the UK and US. The limitation of differential pricing is that it is only effective if affordability levels are greater than the cost of manufacturing, otherwise donor subsidies and government support are required.[151]

- *Patent sharing and voluntary licensing:* As of 2007, 31 voluntary licenses had been issued to generic companies, all but one related to ARVs, which provide restrictive covenants on the rights to produce a patented drug to third party manufacturers.[152] In 2010, the US National Institutes of Health (NIH) licensed patents on Darunavir to the Medicines Patent Pool (MPP), however the NIH license is considered useless for the manufacture and export to countries where Johnson & Johnson has a patent, due to the

[151] (Yadav, 2010, p. 5)

[152] (Amin, 2007 p.3-4.)

company's withdrawal from the MPP.[153] In 2011, Gilead Sciences signed an agreement with the MPP to share intellectual property on a range of medicines to treat HIV. In 2013, ViiV Healthcare, a joint venture between GSK, Pfizer and Shionogi, licensed pediatric formulations of ViiV's existing and pipeline HIV drugs to the MPP.

- *Donations:* In 1987 Merck committed to donate Mectizan, a drug for the treatment of river blindness, for as long as was needed to eliminate the disease. Since 2000, Novartis has been providing free treatment for all leprosy patients that in 2012 it extended by an additional $24.5m commitment. GSK has committed to supply all the albendazole needed to eliminate lymphatic filariasis worldwide by 2020. Pfizer donates medicines to the International Trachoma Initiative (ITI) to eliminate blinding trachoma and to the Diflucan Partnership Program (DPP) to treat cryptococcal meningitis and esophageal candidiasis. However, donation programs have not always been optimally implemented; Pfizer commitment to donate fluconazole in South Africa was partly perceived as an effort to block generically manufactured drugs, being created in response to a generic importation filing and close to the expiration of its patent.[154] Pfizer's donation program was also initially considered to have been too slowly implemented and too restrictive by being limited to the public sector for people with cryptococcal meningitis.[155]

[153] (MSF, 2013)

[154] (KHN, 2001)

[155] (Moraka, 2000)

viii. Pharmaceutical Sector Activities Considered Important in Enhancing Access to Essential Medicines

Corporations are noted to respond to business-society conflicts in four stages: no obligation; social obligation; social responsibility and social responsiveness.[156] No obligation arises from companies perceiving that there is no connection between a social problem and their operations.[157] Social obligation relates to companies responding to the minimally imposed legal or economic constraints.[158] Social responsibility exists when a firm performs in accordance with prevailing social norms, values, performance and expectations.[159] Social responsiveness relates to companies anticipating changes arising from current activities or emerging social problems.[160] With regards to sweatshops, the athletic, footwear and apparel industries evolved from a perception of no obligation prior to 1989, to a perception of a social obligation between 1989-1995, to an understanding of social responsibility after 1995.[161] Below is a generalization of activities across the pharmaceutical sector considered important in enhancing access to essential medicines..

Category	Social Obligation	Social Responsibility	Social Responsiveness
Leadership and governance [162] [163] [164]	• Refrain from conduct that encourages States to not act to promote right to health.	• Existence of code of conduct in relation to access to medicine endorsed by board of directors and top management. • Adopt publicly available and objective human rights policy recognizing right to health and access to medicine.	• Clear board accountability for management of access to medicine. • Practices exposed to public scrutiny through independent verification and accountability under a cooperative oversight model representative of different constituencies. • Systematic disclosure of access to medicine information.

[156] (Sethi, 2003 p.69)

[157] (Sethi, 2003 p.69)

[158] (Sethi, 2003 p.69)

[159] (Sethi, 2003 p.69)

[160] (Sethi, 2003 p.69)

[161] (Sethi, 2003, pp. 28 - 75)

[162] (Pharmaceutical Shareowners Group, 2004 p.13)

[163] (Sethi, 2003 p.199-216)

[164] (Hunt, 2008 p.1-25)

Category	Social Obligation	Social Responsibility	Social Responsiveness
		• Integration of human rights into strategies, policies, programs, projects and activities. • Policies recognize needs of disadvantaged communities and populations. • Clear delegation of authority for management of access to medicine. • Not utilizing transfer pricing practices for tax avoidance purposes.	
Pricing[165] [166] [167] [168]	• Differential prices on case-by-case basis. • Product donations.	• Preferential prices to all developing countries. • Price reductions limited to one or two disease initiatives. • Differential prices not publicly available.	• Systematic, transparent, predictable and tiered global pricing for products. • Offer conditions published. • Prices are affordable to majority of population in developing countries. • Price reductions cover range of products relevant to health priorities in developing countries. • Disclose absolute quantity and value of donations, number of patients treated and donation tax benefit derived.
Patents[169] [170] [171] [172]	• Taking action against patent infringements in developing countries on a case-by-case basis.	• Issue voluntary or royalty-free licenses. • Not applying for patents in least developed countries. • Ownership rights of intellectual property	• Refrains from enforcing patents in developing countries that will exacerbate health problems. • Supports lifting TRIPS restrictions on export of generic versions of patented medicines

[165] (Bluestone et al., 2002 p.12-13)

[166] (CoreRatings, May 2003 p.11)

[167] (Hunt, 2008 p.1-25)

[168] (Back & Saad, 2008, p. 10)

[169] (Bluestone et al., 2002 p.14-21)

[170] (CoreRatings, May 2003 p.13)

[171] (M Moran et al., 2011 p.85)

[172] (Hunt, 2008 p.1-25)

Category	Social Obligation	Social Responsibility	Social Responsiveness
		negotiated on case-by-case basis for JPPI drugs. • Responsible patenting of traditional medicines. • Access to proprietary research tools and databases. • Sharing compound libraries with public and not-for profit groups. • Consent to National Drug Regulatory Authorities using test data in least developed countries.	in developing countries with no patent in force. • Patents foregone for products developed under JPPIs for infectious diseases.
Lobbying[173] [174]	• Transparency in payments to and from developing country governments. • Compliance with state and national laws, including anti-corruption laws.	• Discloses to shareholders lobbying position on patents and related expenditure. • Respects TRIPS flexibilities. • Policies support good governance and pro-poor policy environments.	• Does not lobby for stronger patent protection than mandated by TRIPS or for weaker public health safeguards. • Publicly discloses lobbying position on patents and related expenditure. • Supports building and investment in local capacity and health infrastructure. • Does not lobby for stronger intellectual property rights in relation to the Trans-Pacific Partnership Agreement.
Joint Public Private Initiatives (JPPIs)[175] [176] [177] [178]	• JPPIs commitments are for a limited term. • JPPI emphasis is on product donations.	• JPPIs involve long-term commitments to resolve targeted health problems. • JPPIs targeted to select countries or conditions, despite potential for wider effect.	• JPPIs integrated in business policies. • JPPIs involve indefinite commitments to resolve targeted health problems. • JPPIs don't exclude vulnerable populations. • JPPI objectives include

[173] (Bluestone et al., 2002 p.15-16)

[174] (DFID, 2005 p.14)

[175] (Bluestone et al., 2002 p.18-19)

[176] (Gruskin & Raad, 2010 p.2)

[177] (M Moran et al., 2011 p.85)

[178] (Hunt, 2008 p.1-25)

Category	Social Obligation	Social Responsibility	Social Responsiveness
		• No reporting on impact. • JPPIs work through an existing administrative structure. • Organize conferences on neglected disease topics.	strengthening national health systems • JPPI focus on community participation and empowerment • Clear reporting on impact. • Governance of JPPIs is transparent and any conditions detailed. • Partnership interests fully disclosed.
Research and Development[179] [180] [181]	• Company publishes proportion of R&D expenditure on infectious diseases.	• Public commitment to contribute to research and development for neglected diseases. • Involved in JPPIs addressing R&D for infectious diseases • Publishes target R&D expenditure on infectious diseases. • Donate equipment. • Provide training courses for developing country researchers at academic institutions. • Seeking approval for new drug compounds in non-US markets prior to approval from US Food and Drug Administration (FDA) and the EU's European Medicines Agency (EMEA). • Participate on scientific advisory or management boards of organizations conducting neglected disease research. • Evaluate new compounds proposed by external partners. • Expand research into pediatric formulations.	• Involved in JPPIs addressing R&D for Type I, II and III diseases in relation to developing countries. • Company publishes target and actual R&D expenditure on Type I, II and III diseases in relation to developing countries.

[179] (Bluestone et al., 2002 p.20-21)

[180] (M Moran et al., 2011 p.85)

[181] (Back & Saad, 2008, p. 17)

Category	Social Obligation	Social Responsibility	Social Responsiveness
Product Testing[182] [183]	• Corporate responsibility acknowledged where regulations are weak.	• Compliance with ICH Guidelines for Good Clinical Practice.	• Compliance with WHO Guidelines for Good Clinical Practice for drug trials and Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects. • Full results of all clinical trials published in registry accessible to third parties in accordance with 2012 International Standards for Clinical Trial Registries, World Health Organization.
Product Marketing[184] [185] [186]	• Corporate responsibility acknowledged where regulations are weak.	• Compliance with IFPMA Code of Pharmaceutical Marketing Practices • Transparent product labeling and distribution traceability	• Compliance with WHO Ethical Criteria for Medicinal Drug Promotion. • Ethical promotion complaints upheld reported to shareholders. • Publicly disclose promotional and marketing policies, activities and costs.
Drug Safety Monitoring[187]	• Corporate responsibility acknowledged where regulations are weak.	• Spontaneous reporting and response to adverse events.	• Active drug safety monitoring by company for products introduced as warranted. • Disclosure of adverse drug reactions to regulatory authorities and WHO in all relevant countries.
Product Delivery[188] [189] [190] [191]	• Support sustainability of developing country governments through	• Provide training in developing countries to health care providers.	• Comply with current World Health Organization Good Manufacturing Practice

[182] (Bluestone et al., 2002 p.23-24)

[183] (Hunt, 2008 p.1-25)

[184] (Bluestone et al., 2002 p.23-24)

[185] (CoreRatings, May 2003 p.13)

[186] (Hunt, 2008 p.1-25)

[187] (Bluestone et al., 2002 p.23-24)

[188] (Wu, 2012 p.97)

[189] (M Moran et al., 2011 p.85)

[190] (DFID, 2005 p.14)

Category	Social Obligation	Social Responsibility	Social Responsiveness
	prompt payment of local taxes.		Guidelines • Mode of medicine delivery is respectful of medical ethics and culturally appropriate for target patient group. • Packaging is suited to local environment conditions and addresses counterfeiting. • Collaborate with national medicines procurement, storage and distribution systems in developing countries. • Medicines available without discrimination. • Explore production opportunities in developing countries. • Product unit sales by index country.

[191] (Hunt, 2008 p.1-25)

ix. Analysis of alternative industry change approaches

The ATMi is one of several approaches that have been adopted in an effort to change industry practices, each with varying levels of success. Eight approaches have been examined and are summarized below, including: market incentive / award schemes, voluntary public commitment / membership schemes, legislative mandates, actionable governance indicators, investment indices, voluntary reporting guidelines, voluntary reporting standards and product labeling schemes. Although the approaches are presented and analyzed individually, different approaches have been combined; the Transportation Recall Enhancement, Accountability and Documentation Act of 2000 (legislation) created the car rollover ratings (actionable governance indicator) on showroom new-car stickers (product labels). Each individual approach has its corresponding strengths and weaknesses specific to the problem or issue being addressed; a generalization follows of the common themes:

1. *Market incentive or award schemes,* such as the Malcolm Baldridge National Quality Award, are useful for spurring continued innovation. An incentive or award scheme can help to promote a leading standard and redirect company investments. Participation levels however can be limited due to capacity, scale and funding challenges and a focus on rewarding a small number of leaders may not necessarily facilitate industry wide changes.

2. *Voluntary public commitments / associations,* such as the United Nations Global Compact, Fair Labor Association and Sustainable Forest Initiative are important in developing international standards across a wide stakeholder group. However, voluntary commitments and associations can have weak and / or subjective standards that are supported by inadequate independent verification, limiting the ability to compare and analyze performance.

3. *Legislative mandates,* such as the Clean Air Act of 1970, have been effective in promoting minimum standards. Legislative mandates however may not incentivize continued innovation, can be associated with significant implementation and enforcement costs, require significant political capital to develop, and are limited by national borders. “Problems that are widely dispersed and locally variable, or characterized by wide

differences in consumers' and citizens' preferences, may not lend themselves to uniform rules, subsidies, or taxes."[192]

4. *Actionable governance indicators (AGI),* such as the ATMi, Carbon Disclosure Project (CDP), World Bank 'Doing Business' (DB), Freedom House 'Freedom in the World' (FIW), Aid Transparency Index (ATI), and Transparency International 'Corruption Perceptions Index' (CPI) aggregate information from different sources into a format intended to holistically capture and benchmark performance to empower user decision making. AGIs distil complex data into simple ratings and present the information in a format designed to be user-centered, allowing performance to be understood, compared and acted upon.[193] AGIs however can involve a degree of subjectivity in the weightings and measures applied which can limit the ability to action results when not supported by full transparency.

5. *Investment indices,* such as the Dow Jones Sustainability Index, FTSE4Good and Calvert Social Index, utilize screening criteria to group companies with similar investment characteristics. However, investment indices can have low correlations, weak predictive validity, non-transparent methodologies and don't detail relative or absolute performance.[194] [195] FTSE4Good ESG Ratings (another AGI example) is acknowledged as one example of emerging systems associated with investment indices that quantitatively measure and compare the risk and performance of environmental, social, governance (ESG) performance.

6. *Voluntary reporting guidelines,* such as the Global Reporting Initiative (GRI), are intended to promote transparency by standardizing the reporting of performance. Although relative performance is denoted by ratings, ratings are a reflection of the level of transparency rather than performance. Information users are required to analyze reported information to evaluate and compare performance, which can be challenging within and across sectors.

[192] (Fung et al., 2007, p. 14)

[193] (Fung et al., 2007, p. 2)

[194] (Chatterji & Levine, 2006, pp. 41, 48)

[195] (Chatterji & Levine, 2007, p. 1)

7. *Voluntary reporting standards*, such as SA 8000 and ISO 14000, are designed to provide absolute rather than relative levels of performance. Voluntary reporting standards signal a generic cross-sector minimal level of conformance that is independently verified, but do differentiate between different performance levels.

8. *Product label initiatives*, such as Energy Star, are focused on empowering consumers by providing information at the point of purchase. Product labels however provide limited information to investors and do not attest to the operations of entire organizations.

x. Industry Change Examples

Category	Scope	Example	Theory of Change	Achievements	Strengths	Limitations
Market incentives / Award scheme	National since 1987	Malcolm Baldrige National Quality Award	Guide, evaluate and recognize leading overall organizational quality	• 33-plus state, local, and sector Baldrige-based programs.[196] • Inspired 106 international quality programs.[197] • Every public $1 spent on the Baldrige Program, provides $820 in benefits to the U.S. economy.[198]	• Objective evaluation criteria and process. • Multi-sector initiative.	• Draws attention to best performers, not laggards. • Limited capacity / scale; 69 and 39 national applicants in 2011 and 2012 respectively.[199]
Voluntary public commitment / associations	International since 2000	United Nations Global Compact	Voluntary commitment to continuously improve implementation of key principles	• Over 10,000 corporate participants in over 130 countries.[200]	• Annual reporting of progress requirement by participants.	• Lack of standardized reporting measures to compare performance. • Performance not verified.
Legislative mandates	National since 1970	Clean Air Act of 1970	Mandate minimum standard through legislation; Limit industrial emissions	• Reduced 60% of dangerous air pollutants that cause	• Mandated and enforced minimum standards.	• Requires government intervention that is not always

[196] (Department_of_Commerce, 2012, p. 14)

[197] (Department_of_Commerce, 2012, p. 14)

[198] (Department_of_Commerce, 2012, p. 15)

[199] (NIST, 2013)

[200] (UNGC, 2013)

Category	Scope	Example	Theory of Change	Achievements	Strengths	Limitations
				smog, acid rain and lead poisoning.[201] • New cars today generate 98% less smog-forming pollutants than in 1970.[202]	• Monetizable benefits exceeded the direct compliance costs by four to one.[203]	politically feasible. • Costly to implement. • Does not incentivize continued innovation.
Actionable governance indicators	International since 2008	Carbon Disclosure Project	Collects, standardizes, and reports corporate behavior information on climate change and water scarcity, on behalf of market forces, including shareholders and purchasing corporations	• Almost 6,000 company respondents.[204] • 655 financial institutions with assets of US$78 trillion were signatories to the CDP 2012.[205]	• Carbon Disclosure Leadership Index (CDLI) recognizes the top-scoring 10% of respondents. • Multi-sector initiative. • Detailed scoring methodology.	• Third party verification is not required, but is encouraged as part of the CDP scoring methodology.
Investment Indices	International since 2001	FTSE4Good	Influence investment markets to recognize better corporate environmental and social practice	• Over $10.1 trillion of assets under management incorporate ESG.[206] • 52.3% return for FTSE4Good Global	• Selection criteria is raised every year. • 288 companies removed from index for failure to meet inclusion standards.[208]	• Targeted only toward investors. • FTSE4Good ESG Ratings providing absolute and relative scores are available for paid subscription.

[201] (EPA, 2013)

[202] (EPA, 2013)

[203] (EPA, 1999, p. v)

[204] (CDP, 2012, p. 2)

[205] (CDP, 2012, p. 3)

[206] (FTSE, 2011, p. 7)

Category	Scope	Example	Theory of Change	Achievements	Strengths	Limitations
				Index (USD total return since launch)[207]	• 793 companies added to index since launch.[209]	
Voluntary reporting guidelines	International since 2000	Global Reporting Initiative (GRI)	Mainstream standardized and integrated sustainability reporting	• 2,304 GRI reports published in 2011.[210]	• Provides sector specific guidance.	• Third party verification is not required, but is encouraged as part of the GRI scoring methodology.
Voluntary reporting standards	International since 1998	SA 8000	Creates common language for measuring social compliance	• Over 1.4 million workers are employed in SA8000-certified facilities, across 65 industrial sectors.211	• Universal application regardless of company size, location and sector. • Certification requires third party verification.	• Accountability standards are fragmented across different providers / certifiers.
Product label initiatives	National since 1992	Energy Star	Empower consumers through product labeling to save money and protect the environment.	• Over 60 Energy Star product categories.[212] • 12,600 Energy Star certified buildings.[213] • 80% public awareness	• Strict guidelines set by EPA and US Department of Energy. • All products must be	• Product rather than organizational specific.

[208] (FTSE, 2011, p. 11)

[207] (FTSE, 2011, p. 11)

[209] (FTSE, 2011, p. 11)

[210] (GRI, 2013)

[211] (SAI, 2010)

[212] (EnergyStar, 2013)

[213] (EnergyStar, 2013)

Category	Scope	Example	Theory of Change	Achievements	Strengths	Limitations
				of Energy Star label.[214]	certified by EPA-recognized certification body (CB) and subject to ongoing verification testing.[215]	

[214] (EnergyStar, 2013)

[215] (EnergyStar, 2013)

xi. AGI leading practices

AGIs need to embody a credible compromise that delicately navigates competing interests to motivate desired actions by users and in turn positively influence the behaviors of disclosers. Users represent the most important component in designing AGIs, however additional important considerations include the needs and abilities of disclosures, and the credibility of both the rating system and agency:

- *Clear theory of change:* AGIs need to clearly specify what their purpose, mission and vision. Purpose relates to the change desired, mission relates to the strategy to effect the change and vision relates to their conception of the desired future state.

- *Need for user centered policies:* AGIs need to focus both on the needs and interests of information users and their ability to comprehend the information provided, as well as the needs, interests and capacities of disclosing organizations.216 "They seek to embed new facts in the decision-making routines of information users and to embed user responses into the decision making of disclosers."[217] Embedding new information in user's decision making requires the information to be valued, acquired at a low cost, available when and where decisions are made, that is comprehensible, and connected to a perceived immediate or long-term gain.

- *Need for specified targets, scope and structure:* The specific entities or organizations that are viewed as responsible for the policy problem need to be clearly defined.[218] In addition, the boundaries of information disclosure need to be clearly specified.[219] Data disclosed needs to be standardized in terms of content and format in order to be comparable.[220]

- *Importance of actionable and timely indicators:* AGIs are intended to capture information to spur action rather than measure outcomes; "…means of capturing information on the

[216] (Fung et al., 2007, p. 11)

[217] (Fung et al., 2007, p. 11)

[218] (Fung et al., 2007, p. 41)

[219] (Fung et al., 2007, p. 42)

[220] (Fung et al., 2007, p. 43)

design, capacities, performance and immediate impacts of governance systems rather than longer-term outcomes." [221] The links of indicators to outcomes are complex, possibly subject to long lags and often not well-understood.[222] The relationship of an indicator to outcomes is not as important as when and how reform is possible given the actionable data with clearly specified discloser targets.[223] As there is no one data source for measuring governance, the nature and dimensions of governance need to be clearly defined and measures designed to capture the relevant information.[224] AGIs need to clarify the link between indicator values and reform action, provided the impact of exogenous factors on indicator values is small.[225] A clear definition is required of how the indicators are constructed, what they measure and the source of raw data.[226] Subjective indicators based on expert perceptions may be difficult to action and change and can be widely dispersed.[227] Review processes and statistical techniques can however mitigate subjective biases.[228] Fact-based data can also require subjective interpretation in the review of information and evidence.[229] Simple rules that summarize objective information have been noted to generally outperform decisions based on the same information plus qualitative information that is accompanied by subjective judgments.[230]

- *Importance of transparency:* Continuous improvement and ongoing research are important to refine and improve what will always be imperfect governance indicators.[231] The meaning of scores or data for aggregate indicators can be difficult to interpret in real terms without accompanying actionable disaggregated information.[232] Public and

[221] (Trapnell, 2011, p. 341)

[222] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 9)

[223] (Trapnell, 2011, pp. 324-325)

[224] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 6)

[225] (Trapnell, 2011, p. 322)

[226] (Trapnell, 2011, p. 323)

[227] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 11)

[228] (Trapnell, 2011, p. 324)

[229] (Trapnell, 2011, p. 324)

[230] (Chatterji, Levine, & Toffel, 2009, p. 164)

[231] (Chatterji & Levine, 2006, p. 48)

[232] (Trapnell, 2011, p. 321)

professional scrutiny of the content and methodology of indicators is essential for the credibility of governance indicators.[233] "Lack of consensus about metrics impairs the credibility of transparency."[234] Rating organizations must also be trusted for a rating system to be effective.[235]

- *Importance of complementary measures:* Complementary measures of a single indicator can potentially result in greater accuracy provided the same concepts are measured consistently.[236] Aggregating several measures into one indicator can reduce errors in sampling and in measuring any individual indicator, aggregation can also mitigate perception biases generated by expert assessments.[237]

- *Acknowledgement of measurement error:* Measurement errors are inherent in all governance indicators due both to intrinsic measurement challenges and the broad nature of governance.[238] Survey sampling errors and variations in opinion can reduce the accuracy of a specific indicator.[239] It is therefore important that survey questions on governance are specific and not open to interpretation.[240] Errors also exist because no one specific indicator can be a perfect measure of broad concepts of governance.[241] Aggregation methods provide the opportunity to calculate a margin of error for both the aggregate indicator itself and its component individual indicators that should be explicitly acknowledged to provide users with a clear indication of whether data can be compared.[242]

[233] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 32)

[234] (Fung et al., 2007, p. 174)

[235] (Fung et al., 2007, p. 57)

[236] (Trapnell, 2011, pp. 319-320)

[237] (Trapnell, 2011, p. 320)

[238] (Kaufmann & Kraay, 2007, p. 24)

[239] (Kaufmann & Kraay, 2007, p. 24)

[240] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 21)

[241] (Kaufmann & Kraay, 2007, p. 24)

[242] (Trapnell, 2011, p. 320)

- *Limited ability to compare performance over time:* Comparisons over time are difficult as methodologies, governance standards and sources of data can change over time.[243] Aggregation of many data points can obscure both successful reforms in particular areas and bad scores.[244]

- *Challenge of prioritization:* Weighting of data points appropriately is difficult and requires a clear understanding of the theoretical relationship between the construct being studied and the measured data points.[245] Absent clear links between indicators and outcomes, it can be difficult to prioritize reform. Inappropriate weightings can create the risk of 'reform illusion,' where isolated changes are made for the sole purpose of showing progress on specific indicators.[246] Weightings applied may also not align with the perspectives of different users.[247]

- *Importance of complete and accurate information:* Voluntary disclosure by business and other organizations can be incentivized by the risk of liability, publicized crises, shifts in public attitudes and competitive dynamics.[248] Only two studies have explored how non-profit organizations respond to independent agent ratings and rakings, with only one study related to the US News And World Report demonstrating that law school rankings did influence management decisions.[249] One study of how for-profit firms respond to non-governmental environmental ratings noted greater relative improvements in poor performing firms that were in highly regulated industries and had low-cost opportunities to exploit.[250] However, the quantity and quality of information that a company voluntarily provides is often inadequate to inform decision making by the public, hence the need for policymakers to push organizations to reveal more.[251] A number of studies

[243] (Trapnell, 2011, p. 320)

[244] (Trapnell, 2011, p. 320)

[245] (Trapnell, 2011, p. 320)

[246] (Kaufmann & Kraay, 2007; Trapnell, 2011, p. 10)

[247] (Chatterji & Levine, 2006, p. 41)

[248] (Fung et al., 2007, p. 38)

[249] (Chatterji & Toffel, 2010, p. 919)

[250] (Chatterji & Toffel, 2010, p. 932)

[251] (Fung et al., 2007, p. 38)

have shown that company management practices and performance do change in response to government mandatory information disclosure programs.[252] One example includes the legislation requiring manufacturers to annually disclose toxic pollution by factory and chemical, which halved pollution levels within the first ten years.[253] Government typically intervenes when information asymmetry either increases the risks borne by the public, impacts the quality of critical services, perpetuates unacceptable discrimination or social inequities, or facilitates corruption.[254] Government involvement is however not always essential, the Carbon Disclosure Project demonstrates the ability of user actions (i.e. investors) to be effectively triggered to cause disclosers (ie. companies) to advance a public good (i.e. by demonstrating improvement in environmental performance).

- *Need for sustainability:* To be sustainable, AGIs need to demonstrate gains in use, accuracy and scope over time.[255] Policies with high political sustainability have the greatest chance of success; a subset of disclosers benefit from disclosure through competitive advantage, and dispersed users of information form political coalitions to press effectively for better disclosure.[256]

[252] (Chatterji & Toffel, 2010, pp. 919-920)

[253] (Fung et al., 2007, p. 29)

[254] (Fung et al., 2007, pp. 40-41)

[255] (Fung et al., 2007, p. 11)

[256] (Fung et al., 2007, pp. 112-113)

xii. ATMi background and 2010 and 2012 results

The ATMi was established based on public online questionnaires and expert roundtable consultations, with stakeholder consultations being repeated every two years. An Expert Review Committee, Technical Subcommittee, and Advisory Committee, consisting of various stakeholder groups active in supporting access to essential medicines, are leveraged to develop and refine the methodology. MSCI ESG Research is responsible for conducting the research and analysis. The MSCI team obtains direct company information via an online questionnaire and email and phone conversations that is then verified against third party information.

The ATMi presently includes only originator pharmaceutical companies, excluding generic providers, biotechnology companies, distribution companies and small to medium sized enterprises (SMEs). The ATMi selects the world's 20 largest pharmaceutical companies based on size, determined primarily but not exclusively on market capitalization as at December 31st, 2011, and portfolio relevance.

The ATMi focuses on 33 priority diseases, consisting of a combination of the top 10 diseases communicable, top 10 non-communicable diseases and 14 neglected tropical diseases based on global disease burden.[257] The index additionally focuses on maternal conditions, neonatal infections and ad hoc regional health challenges.[258] The disease scope is based on global WHO Disability Adjusted Life Years (DALY) data.[259] The scope of products in the index includes medicines, investigational therapeutic and preventative vaccines, diagnostics, microbicides, vector control products and platform technologies.[260]

Each pharmaceutical company is assessed on seven technical areas with a weighted distribution: general access to medicine management (10%); public policy and market influence (10%); research and development (20%); equitable pricing, manufacturing and distribution (25%); patents and licensing (15%); capability advancement in product development and distribution (10%); and product donations and philanthropic activities

[257] (AMI, 2012b, pp. 15-18)

[258] (AMI, 2012b, pp. 15-18)

[259] (AMI, 2012b, pp. 15-18)

[260] (AMI, 2012b, p. 19)

(10%).[261] Each technical area is assessed across four strategic pillars with a weighted distribution: commitments (25%), transparency (25%), performance (40%), and innovation (10%).[262] 101 indicators across the technical areas and strategic pillars are used to develop the index scores.

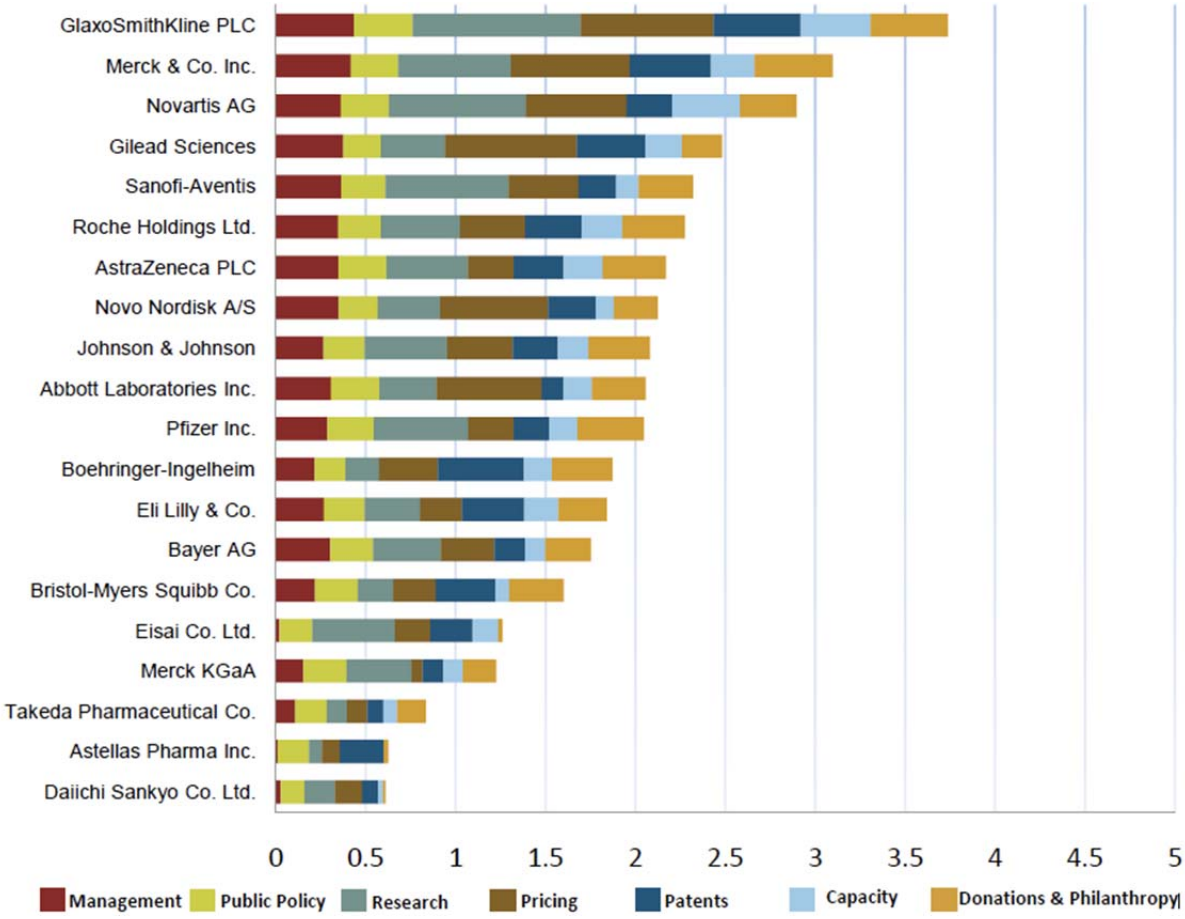
The ATMi is published every two years. In 2008, the ATMi benchmarked the policies and practices of the 17 largest drug originators and three generics. In 2010, the ATMi analyzed 20 drug originators and seven generic companies. The 2012 ATMi was published in November 2012 and analyzed 20 drug originator companies, excluding generics. For each pharmaceutical company ATMi provides an overall score, a score for each technical area and a report card of leading practices, highlights of changes and suggested areas for improvement.

In 2010 GlaxoSmithKline, Merck & Co. and Novartis represented the top ranking pharmaceutical companies in order, while Ranbazy, Cipla and Dr Reddy's represented the top ranking generic companies. In 2012 GlaxoSmithKline was again the leader followed by Johnson & Johnson.

[261] (AMI, 2012b, pp. 23-26)

[262] (AMI, 2012b, pp. 23-26)

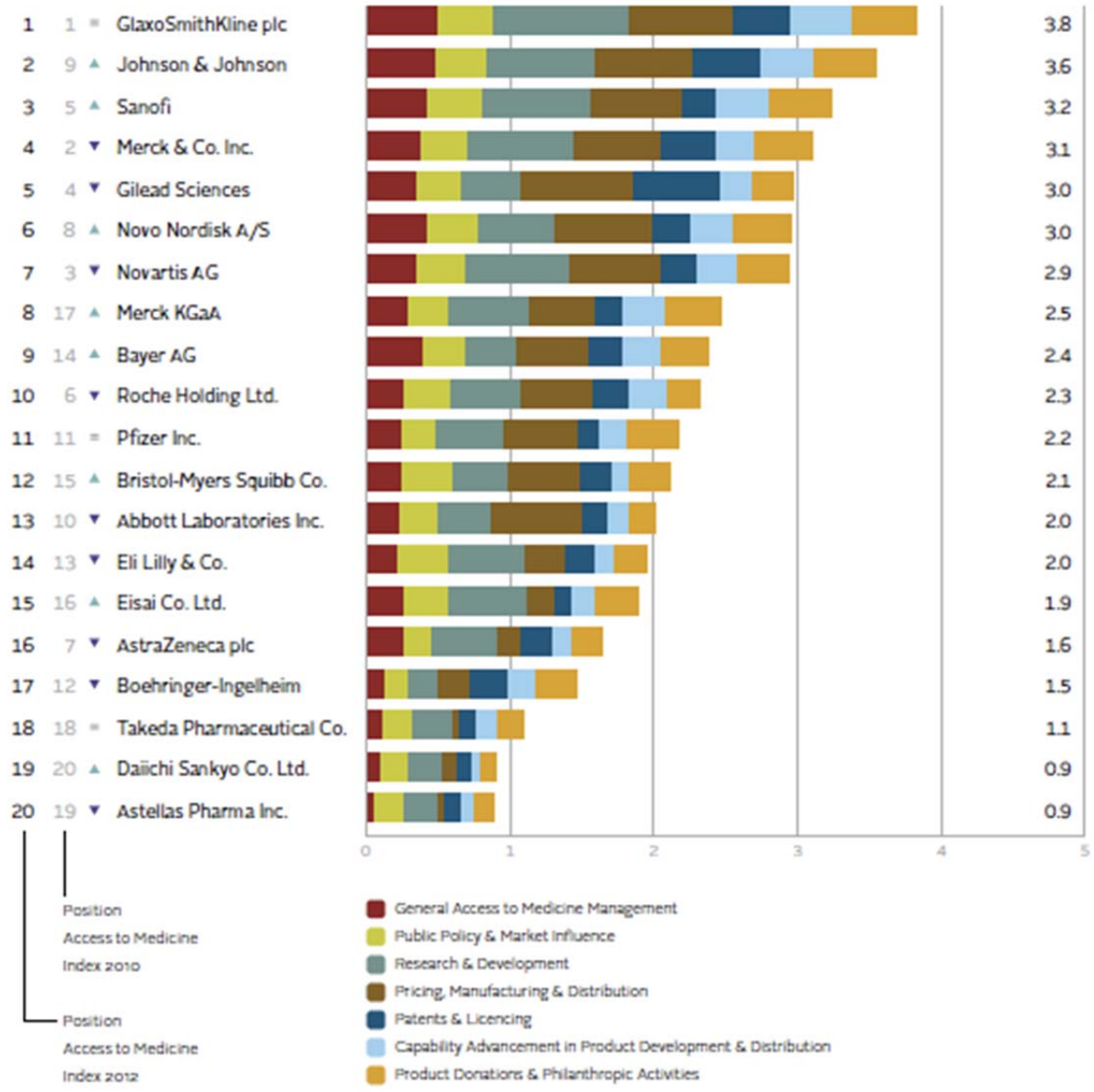
2010 ATMi Results



	Access to Medicine Management	Public Policy and Market Influence	R&D for Index Diseases	Equitable Pricing, Manufacturing & Distribution	Patents and Licensing	Capability Advancement in Product Development & Distribution	Product Donations & Philanthropy	Overall Ranking
Ranbaxy Laboratories Limited	High	Medium	High	High	High	Low	Medium	1
Cipla Limited	Medium	Medium	Medium	Medium	High	High	High	2
Dr. Reddy's	High	High	Medium	Low	Low	Medium	Medium	3
Mylan Inc.	Low	Low	High	High	Low	No evidence found	Low	4
Sun Pharmaceuticals	Low	Low	No evidence found	Low	Low	Medium	No evidence found	5
Teva Pharmaceuticals Ltd	Low	Medium	No evidence found	No evidence found	Low	No evidence found	Low	6

Source: ATMi Index 2010

2012 ATMi Results



Source: ATMi Index 2012

xiii. Study details

Subject Survey A - Interviews

Objective: Obtain independent expert views on important elements in evaluating the performance of the pharmaceutical sector in relation to access to essential medicines.

Target Population: Objective and knowledgeable global health figures focused on improving access to essential medicines.

Time Estimate: 1 hour per interview

Study Approach: Over the phone interview / written survey.

Leading Questions:

- Should health be considered a basic human right? If so, what should the human right to health encompass and how could it best be protected and promoted?
- What do you consider the most important elements to improving access to essential medicines in developing countries?
- What should the role of the pharmaceutical sector be in improving access to essential medicines in developing countries? How should this role evolve in the next five to ten years?
- What are the important characteristics of a pharmaceutical company in promoting an optimal level of access to essential medicines in developing countries?
- What is your awareness and understanding of the ATMi?
- What have you observed to be the reaction to the ATMi by the public, civil society, pharmaceutical companies and investors?
- What do you perceive to be the strengths of the ATMi? What are your suggestions for improving the ATMi?

Subject Survey B - Interviews

Objective: Obtain independent human rights activist views from developing countries on important elements in promoting the human right to health.

Target Population: Objective and knowledgeable human rights figures in developing countries.

Time Estimate: 1 hour per interview

Study Approach: Over the phone interview / written survey.

Leading Questions:

- Should health be considered a basic human right? If so, what should the human right to health encompass and how could it best be protected and promoted?
- What do you consider the most important elements to improving access to essential medicines in developing countries?
- What should be the role of leading NGOs in the south to promote health as a human right? What is necessary to catalyze further action? What questions remain unanswered?
- What should the role of the pharmaceutical sector be in improving access to essential medicines in developing countries? How should this role evolve in the next five to ten years?
- What is your awareness and understanding of the ATMi?
- What have you observed to be the reaction to the ATMi by the public, civil society, pharmaceutical companies and investors?
- What do you perceive to be the strengths of the ATMi? What are your suggestions for improving the ATMi?

Subject Survey C - Interviews

Objective: Understand the minimum requirements necessary for the ATMi to be incorporated into investment criteria.

Target Population: Leading investors that have a focus on social issues as part of their investment fund criteria.

Time Estimate: 1 hour per interview

Study Approach: Over the phone interview / written survey.

Leading Questions:

- What criteria do you utilize to evaluate a potential investment opportunity in a pharmaceutical company?
- What do you consider the social obligations of pharmaceutical companies? Is this an important element in identifying investment opportunities?
- What is your understanding of the issue of access to essential medicines in developing countries?
- Should health be considered a basic human right? If so, what should the human right to health encompass and how could it best be protected and promoted?
- What do you consider to be the role of the pharmaceutical sector in improving access to essential medicines in developing countries? How should this role evolve in the next five to ten years?
- What is your awareness and understanding of the ATMi?
- What would be your minimum requirements for a third party index, such as the ATMi, to be incorporated into investment fund criteria?

Subject Survey D – Interviews

Objective: Obtain perspectives of pharmaceutical companies on the ATMi.

Target Population: Pharmaceutical companies included in the ATMi.

Time Estimate: 1 hour per interview

Study Approach: Over the phone interview / written survey.

Leading Questions:

- Should health be considered a basic human right? If so, what should the human right to health encompass and how could it best be protected and promoted?
- What is the level of senior management, CEO and Board awareness of ATMi?
- What is the level of agreement with ATMi scores published for your company and other companies?

- What is the perceived usefulness / value of ATMi?
- What is the relevance of ATMi to your business operations, partner engagement and hiring?
- What are your suggestions for improving the ATMi?

Subject Survey E – Interview

Objective: Understand approach of ATMi Foundation to effectively engage the public, civil society, pharmaceutical companies and investors.

Target Population: Access to Medicine Foundation

Time Estimate: 2 hours

Study Approach: Over the phone interview / written responses.

Proposed Questions:

- Should health be considered a basic human right? If so, what should the human right to health encompass and how could it best be protected and promoted?
- Are you consistently able to reach an appropriate consensus across the stakeholder roundtables, expert review committee and advisory committee in key decision making? How are conflicts in opinions resolved?
- What is the level of assurance obtained for information submitted by pharmaceutical companies to derive the ATMi? Is information received from pharmaceutical companies independently verified?
- How does the ATMi Foundation determine what information submitted by pharmaceutical companies to publish?
- What is the process for agreeing and finalizing an index score with each respective pharmaceutical company?
- How does the ATMi Foundation communicate its results to the public, pharmaceutical companies (both included and excluded in the index), investors and civil society?
- What social media tools does the ATMi Foundation utilize to engage the public?

- How does the ATMi Foundation engage in investor relations?
- How does the ATMi Foundation engage pharmaceutical companies that participate and don’t participate in the index?
- How does the ATMi Foundation engage civil society?

xiv. ATMi 2012 measurement framework indicator summary

		25% Commitments	25% Transparency	40% Performance	10% Innovation
10%	General Access to Medicine Management	A.I.1 Governance: management structures		A.III.1 Governance: management structures, performance management & incentives	A.IV.1 Innovation in general access to medicine management
		A.I.2 Stakeholder engagement		A.III.2 Stakeholder engagement	
			A.II.1 Strategy: policies & practice A.II.2 Strategy: policies & practice	A.III.3 Strategy: policies & practice	
		A.I.3 Governance: performance management & incentives		A.III.4 Governance: performance management & incentives	
10%	Public Policy and Market Influence	B.I.1 Lobbying	B.II.1 Lobbying B.II.2 Lobbying B.II.3 Lobbying	B.III.1 Lobbying, ethical marketing, anti-bribery/ corruption	B.IV.1 Innovation in public policy & market influence
		B.I.2 Endorses competition	B.II.4 Endorses competition & non-pursuit of data exclusivity	B.III.2 Endorses competition	
		B.I.3 Non-pursuit of data exclusivity			
		B.I.4 Ethical marketing	B.II.5 Ethical marketing	B.III.3 Lobbying, ethical marketing, anti-bribery/ corruption	
		B.I.5 Anti-bribery/corruption	B.II.6 Ethical marketing, anti-bribery/corruption		

		25% Commitments	25% Transparency	40% Performance	10% Innovation
20%	Research and Development		C.II.1 R&D for IDs suitable to the ICs' needs	C.III.1 R&D for IDs suitable to the ICs' needs	C.IV.1 Innovation in R&D
		C.I.1 Innovative and adaptive R&D for IDs	C.II.3 Innovative and adaptive R&D for IDs	C.III.2 Innovative R&D for IDs	
				C.III.3 Adaptive R&D for IDs	
		C.I.3 R&D partnerships conducive to access & IP sharing	C.II.2 R&D partnerships conducive to access & IP sharing	C.III.4 R&D partnerships conducive to access & IP sharing C.III.6 R&D partnerships conducive to access & IP sharing	
				C.III.5 Experimental Indicator	
		C.I.2 Clinical trials conduct	C.II.4 Clinical trials conduct & Accountability for conduct of CROs	C.III.7 Clinical trials conduct	
				C.III.8 IP Sharing	
		C.I.4 Accountability for conduct of CROs	C.II.5 Accountability for conduct of CROs	C.III.9 Accountability for conduct of CROs	
25%	Equitable Pricing, Manufacturing and Distribution	D.I.1 Tiered or equitable pricing schemes D.I.2 Tiered or equitable pricing schemes	D.II.1 Tiered or equitable pricing schemes D.II.2 Tiered or equitable pricing schemes	D.III.1 Tiered or equitable pricing D.III.2 Tiered or equitable pricing schemes	
		D.I.3 Accountability for sales agents' pricing practices			
		D.I.6 Filing for marketing approval/registration for use of products in ICs	D.II.3 Filing for marketing approval/registration for use of products in ICs	D.III.3 Filing for marketing approval/registration for use of products in ICs D.III.5 Filing for marketing approval/registration for use of products in ICs	D.IV.1 Innovation in equitable pricing D.IV.2 Innovation in manufacturing and distribution
		D.I.4 Drug recall policies & practices	D.II.5 Drug recall policies & practices	D.III.4 Drug recall policies & practices	
		D.I.5 Brochure & packaging adaptation		D.III.6 Brochure & packaging adaptation	
			D.II.4 Quality management systems for products for ICs		

		25%	25%	40%	10%
		Commitments	Transparency	Performance	Innovation
15%	Patents and Licensing	E.I.1 Patents not filed in ICs (or binding NADs in place)	E.II.2 Patents not filed in ICs (or binding NADs in place)		E.IV.1 Innovation in patents & licensing
		E.I.2 Fully respects TRIPS flexibilities	E.II.1 Fully respects TRIPS flexibilities	E.III.4 Fully respects TRIPS flexibilities	
		E.I.3 Access-oriented IP/deal-making strategy for ICs	E.II.3 Access-orientated IP/deal-making strategy for ICs	E.III.1 Access-orientated IP/deal-making strategy for Ics	
				E.III.5 Access-orientated IP/deal-making strategy for ICs	
		E.I.4 Transfers technology and uses milestone-based agreements		E.III.2 Transfers technology and uses milestone-based agreements	
				E.III.3 Support for IP sharing (MPP)	
10%	Capability Advancement in Product Development and Distribution	F.I.1 Capacity building in QMS and manufacturing standards		F.III.1 Capacity building in QMS and manufacturing standards	F.IV.1 Innovation in capability advancement in quality control
		F.I.2 Capacity building in R&D		F.III.2 Capacity building in R&D	
		F.I.3 Capacity building in supply chain management		F.III.3 Capacity building in supply chain management	F.IV.2 Innovation in capability advancement in research product development and other capacities
		F.I.4 Capacity building in pharmacovigilance	F.II.1 Capacity building in pharmacovigilance	F.III.4 Capacity building in pharmacovigilance	
				F.III.5 Initiatives to build other capacities	
10%	Product Donations & Philanthropic Activities	G.I.1 Policies and practice in relation to drug donations	G.II.1 Policies and practice in relation to	G.III.2 Policies and practice in relation to drug donations	G.IV.1 Innovation in product donations
		G.I.2 Policies and practice in relation to drug donations	G.II.2 Policies and practice in relation to drug donations	G.III.3 Policies and practice in relation to drug donations	
		G.I.3 Sustainable philanthropy	G.II.3 Sustainable philanthropy	G.III.4 Sustainable philanthropy	
		G.I.4 Commitment to single-drug donation programmes		G.III.1 Experimental Indicator Commitment to single-drug donation programmes	

Source data: ATMi Methodology Report 2012 Stakeholder Review – May 2012

xv. Top DALYs ('000s) in LMIC and LIC (3% discounting, Age weights)

Cause	CD vs NCD	WORLD DALY	TOTAL DALY in LMIC and LIC	Medicines Available	In AMI	In EML
Lower respiratory infections	CD	94 511	91 088	Y	Y	Y
Diarrhoeal diseases	CD	72 777	71 005	Y	Y	Y
Unipolar depressive disorders	NCD	65 472	50 058	Y	Y	Y
HIV/AIDS	CD	58 513	47 772	Y	Y	Y
Ischaemic heart disease	NCD	62 587	44 860	Y	Y	Y
Prematurity and low birth weight	CD	44 307	41 997	Y	N	Y
Birth asphyxia and birth trauma	CD	41 684	39 962	N	N	N/A
Neonatal infections and other	CD	40 433	38 772	Y	Y	Y
Cerebrovascular disease	NCD	46 591	35 600	Y	Y	N
Malaria	CD	33 976	33 862	Y	Y	Y
Tuberculosis	CD	34 217	31 591	Y	Y	Y
Chronic obstructive pulmonary	NCD	30 196	25 074	Y	Y	Y
Refractive errors	NCD	27 745	23 533	N	N	N/A
Congenital abnormalities	NCD	25 280	21 646	Y	N	N
Hearing loss, adult onset	NCD	27 356	20 929	N	N	N/A
Protein-energy malnutrition	CD	17 462	16 750	Y	N	Y
Cataracts	NCD	17 757	16 204	N	N	N/A
Alcohol use disorders	NCD	23 738	16 004	Y	N	N
Measles	CD	14 853	14 812	Y	Y	Y
Iron-deficiency anaemia	CD	16 152	14 714	Y	N	Y
Schizophrenia	NCD	16 769	13 805	Y	N	N
Diabetes mellitus	NCD	19 705	13 551	Y	Y	Y
Asthma	NCD	16 317	12 921	Y	Y	Y
Bipolar affective disorder	NCD	14 425	11 623	Y	N	Y
Meningitis	CD	11 426	10 975	Y	Y	Y
Osteoarthritis	NCD	15 586	10 913	Y	Y	N
Cirrhosis of the liver	NCD	13 640	10 012	Y	Y	N
Pertussis	CD	9 882	9 739	Y	Y	Y
Nephritis/nephrosis	NCD	9 057	7 712	Y	Y	N
Nutritional/endocrine disorders	NCD	10 446	7 584	Y	N	Y
Abortion	CD	7 424	7 142	Y	Y	N
Macular degeneration and other	NCD	9 297	7 034	Y	N	N
Trachea/bronchus/lung cancers	NCD	11 766	6 732	Y	N	N
Epilepsy	NCD	7 854	6 615	Y	Y	N
Hypertensive heart disease	NCD	8 020	6 391	Y	N	Y
Maternal sepsis	CD	6 535	6 152	Y	Y	N
Lymphatic filariasis	CD	5 941	5 928	Y	Y	N
Alzheimer and other dementias	NCD	11 158	5 727	Y	N	N
Stomach cancer	NCD	7 491	5 667	Y	N	N
Migraine	NCD	7 765	5 614	Y	N	N

Source: WHO Global Burden of Disease 2004 (2008 Update)

xvi. Projected 2030 Top DALYs ('000s) in LMIC and LIC (3% discounting, Age weights)

Cause	CD vs NCD	WORLD DALY	TOTAL DALY in LMIC and LIC
Unipolar depressive disorders	NCD	84 784	68 590
Ischaemic heart disease	NCD	75 450	59 520
Cerebrovascular disease	NCD	58 205	48 185
Chronic obstructive pulmonary disease	NCD	51 876	47 166
Lower respiratory infections	CD	43 800	41 872
Refractive errors	NCD	36 911	32 379
Hearing loss, adult onset	NCD	39 584	31 905
HIV/AIDS	CD	34 139	27 148
Neonatal infections and other conditions	CD	25 425	24 782
Birth asphyxia and birth trauma	CD	25 340	24 663
Prematurity and low birth weight	CD	25 389	24 469
Cataracts	NCD	25 377	23 525
Diabetes mellitus	NCD	30 890	21 991
Diarrhoeal diseases	CD	21 610	20 923
Alcohol use disorders	NCD	25 385	18 327
Osteoarthritis	NCD	21 752	16 124
Asthma	NCD	19 188	15 881
Congenital abnormalities	NCD	17 683	15 384
Schizophrenia	NCD	18 003	15 281
Tuberculosis	CD	15 666	14 889
Trachea/bronchus/lung cancers	NCD	19 385	14 338
Malaria	CD	12 897	12 751
Bipolar affective disorder	NCD	15 111	12 616
Macular degeneration and other	NCD	15 446	12 457
Alzheimer and other dementias	NCD	18 989	10 567
Nephritis/nephrosis	NCD	10 379	8 945
Hypertensive heart disease	NCD	10 424	8 687
Stomach cancer	NCD	10 307	8 428
Liver cancer	NCD	9 204	8 066
Cirrhosis of the liver	NCD	10 654	7 683
Nutritional/endocrine disorders	NCD	9 837	7 394
Glaucoma	NCD	8 263	7 099
Drug use disorders	NCD	9 699	7 068
Protein-energy malnutrition	CD	7 209	6 951
Oesophagus cancer	NCD	7 425	6 685
Iron-deficiency anaemia	CD	7 182	6 494
Epilepsy	NCD	7 437	6 351
Panic disorder	NCD	7 644	6 333
Breast cancer	NCD	8 929	6 286
Migraine	NCD	7 583	5 634

Source: WHO Global Burden of Disease 2004 (2008 Update)

xvii. Evaluation of 2012 ATMi Indicators for Completeness and Accuracy

Category	Suggested Measures for Inclusion	Suggestions for Strengthening Leading Practice Standard
General Access to Medicine Management[263] [264] [265]	• Practices exposed to public scrutiny through independent verification and accountability under a cooperative oversight model representative of different constituencies. • Existence of code of conduct in relation to access to medicine endorsed by board of directors and top management. • Publicly disclose objective human rights policy recognizing right to health and access to medicine. • Integration of human rights into strategies, policies, programs, projects and activities. • Policies recognize needs of disadvantaged communities and populations.	• A.II.1. Should specify the systematic (i.e. standardized and complete) information required to be disclosed in terms of access to essential medicines by country and product. • A.III.2 Should recognize participation on scientific advisory or management boards of organizations conducting neglected disease research.
Public Policy & Market Influence [266] [267]	• Policies support good governance and pro-poor policy environments. • Not lobbying for stronger intellectual property rights in relation to the Trans-Pacific Partnership Agreement. • Not utilizing transfer pricing practices for tax avoidance purposes	• B.II.1 Disclosure of advocacy activities should require100% of index countries to be covered rather than half. • B.II.5: Promotional and marketing policies, activities and costs should be publicly disclosed. • B.III.2 Anti-competitive behavior should include all anticompetitive practices across globe, rather than excluding IP anticompetitive behavior and being limited to only index countries.
Research & Development [268]	• Seeking approval for new drug compounds in non-US markets prior to obtaining FDA and EMEA approval.	• C.II.1 Company should publish target and actual R&D expenditure on Type I, II and III diseases in relation to

[263] (Pharmaceutical Shareowners Group, 2004 p.13)

[264] (Sethi, 2003 p.199-216)

[265] (Hunt, 2008 p.1-25)

[266] (Bluestone et al., 2002 p.15-16)

[267] (DFID, 2005 p.14)

[268] (Bluestone et al., 2002 p.20-21)

Category	Suggested Measures for Inclusion	Suggestions for Strengthening Leading Practice Standard
[269] [270] [271] [272] [273] [274] [275]	• Expand research into pediatric formulations.	developing countries on an annual basis. • C.II.4 Full results of all clinical trials should be published in registry accessible to third parties in accordance with 2012 International Standards for Clinical Trial Registries, World Health Organization. • C.III.9 Should comply with WHO Guidelines for Good Clinical Practice for drug trials.
Manufacturing and Distribution [276] [277] [278] [279] [280] [281] [282]	• Support sustainability of developing country governments through prompt payment of local taxes. • Transparent product labeling and distribution traceability • Prices are affordable to majority of population in developing countries. • Price reductions cover range of products relevant to health priorities	• D.I.6 Marketing approval and product registration should be obtained before product launch rather than up to 12 months after product launch. • D.II.2 Should require systematic, transparent, predictable and tiered global pricing for products, rather than average prices for certain tiers or percentage reduction.

[269] (M Moran et al., 2011 p.85)

[270] (Bluestone et al., 2002 p.23-24)

[271] (Hunt, 2008 p.1-25)

[272] (Bluestone et al., 2002 p.23-24)

[273] (Wu, 2012 p.97)

[274] (M Moran et al., 2011 p.85)

[275] (Back & Saad, 2008, p. 17)

[276] (Bluestone et al., 2002 p.12-13)

[277] (CoreRatings, May 2003 p.11)

[278] (Hunt, 2008 p.1-25)

[279] (Bluestone et al., 2002 p.23-24)

[280] (CoreRatings, May 2003 p.13)

[281] (Hunt, 2008 p.1-25)

[282] (Back & Saad, 2008, p. 10)

Category	Suggested Measures for Inclusion	Suggestions for Strengthening Leading Practice Standard
	in developing countries. • Ethical promotion complaints upheld reported to shareholders. • Comply with current World Health Organization Good Manufacturing Practice Guidelines • Mode of medicine delivery is respectful of medical ethics and culturally appropriate for target patient group. • Packaging is suited to local environment conditions and addresses counterfeiting. • Active drug safety monitoring by company for products introduced as warranted. • Disclosure of adverse drug reactions to regulatory authorities and WHO in all relevant countries. • Explore production opportunities in developing countries. • Provide training in developing countries to health care providers. • Product unit sales by index country.	• D.II.2 Offer conditions should be published detailing any distribution restrictions. • D.III.1 Equitable/tiered pricing programs should span 100% of index countries for relevant health priorities.
Patents and Licensing [283] [284] [285] [286]	• Responsible patenting of traditional medicines. • Patents foregone for products developed under JPPIs for infectious diseases.	• E.I.1 Commitment to not file patents should be for all index countries or at least all developing countries, rather than being limited to LDCs. • E.I.1. Should refrain from enforcing patents in developing countries that will exacerbate health problems.
Capability Advancement in Product	• Governance of JPPIs is transparent and any conditions detailed. • JPPIs don't exclude vulnerable populations. • Clear reporting on outcomes and impact of JPPIs.	• F.III.2 / F.III.3 / F.III.4 / F.III.5 JPPIs should involve indefinite commitments to resolve targeted health problems by eradicating disease(s).

[283] (Bluestone et al., 2002 p.14-21)

[284] (CoreRatings, May 2003 p.13)

[285] (M Moran et al., 2011 p.85)

[286] (Hunt, 2008 p.1-25)

Category	Suggested Measures for Inclusion	Suggestions for Strengthening Leading Practice Standard
Development and Distribution [287] [288] [289]	• Partnership interests fully disclosed. • Consent to National Drug Regulatory Authorities using test data in least developed countries.	
Drug Donations and Philanthropic Activities [290] [291] [292]	• Disclosure of donation tax benefit derived.	• G.III.4 Alignment of philanthropic activities with national health system development plans should be stated in percentage, rather than absolute terms.

[287] (Bluestone et al., 2002 p.18-19)

[288] (Gruskin & Raad, 2010 p.2)

[289] (M Moran et al., 2011 p.85)

[290] (Bluestone et al., 2002 p.12-13)

[291] (CoreRatings, May 2003 p.11)

[292] (Hunt, 2008 p.1-25)

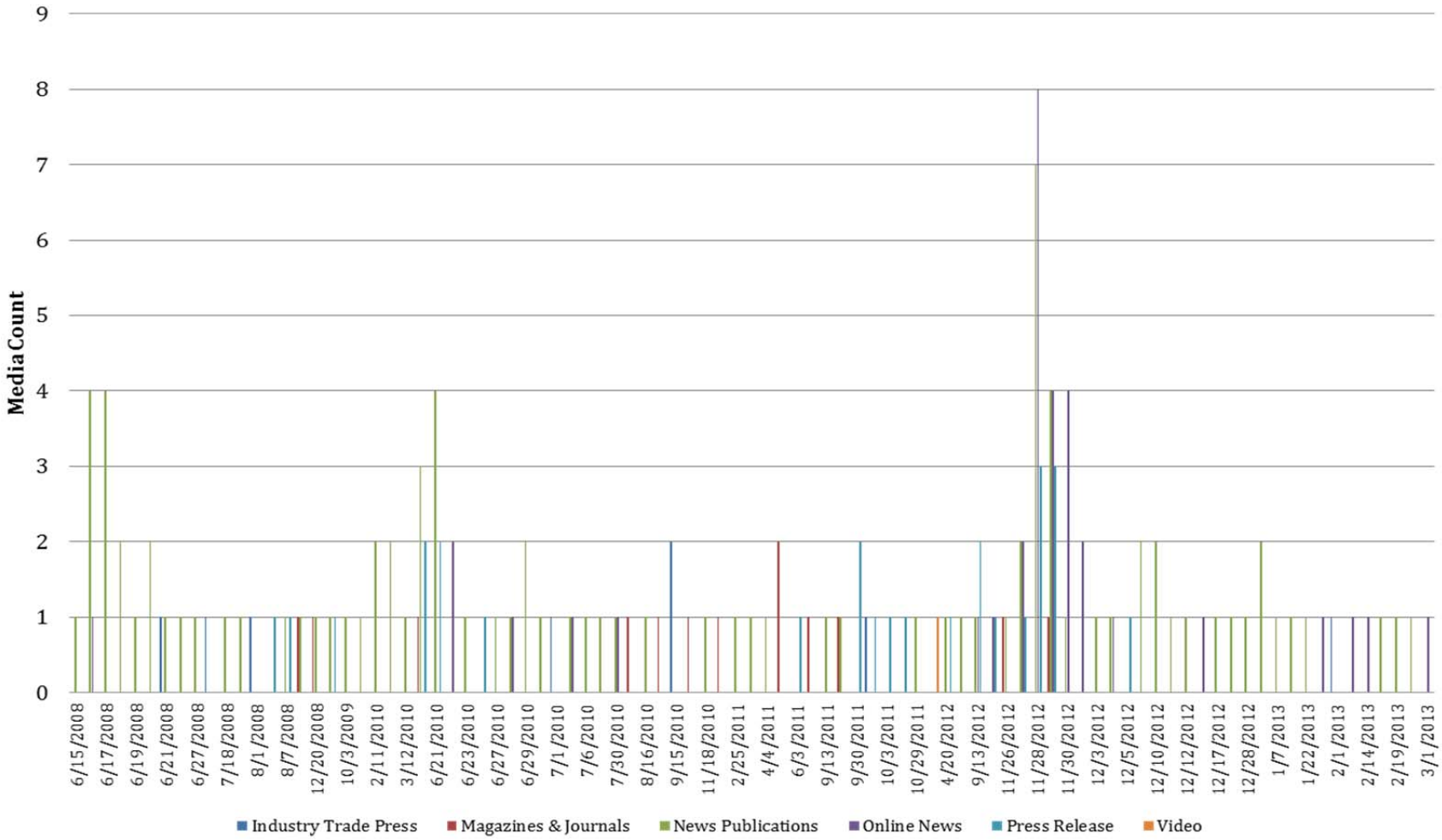
xviii. Evaluation of 2012 ATMi Indicators

The following represents an evaluation of all 101 indicators and their corresponding scoring scales detailed fully in the Access to Medicine Index 2012 Report, pages 112 to 133.

	Indicator	Specific	Data Source
General Access to Medicine Management	A.I.1	Y	N
	A.I.2	Y	Y
	A.I.3	Y	Y
	A.II.1	Y	Y
	A.II.2	N	Y
	A.III.1	Y	N
	A.III.2	Y	N
	A.III.3	Y	N
	A.III.4	Y	N
	A.IV.1	Y	N
Public Policy and Market Influence	B.I.1	N	N
	B.I.2	Y	Y
	B.I.3	N	N
	B.I.4	Y	N
	B.I.5	Y	Y
	B.II.1	Y	Y
	B.II.2	N	Y
	B.II.3	Y	Y
	B.II.4	N	Y
	B.II.5	N	Y
	B.II.6	Y	Y
	B.III.1	Y	N
	B.III.2	Y	N
	B.III.3	Y	N
	B.IV.1	Y	N
Research and Development	C.I.1	N	N
	C.I.2	N	N
	C.I.3	N	N
	C.I.4	Y	Y
	C.II.1	N	Y
	C.II.2	Y	Y
	C.II.3	Y	Y
	C.II.4	Y	Y
	C.II.5	Y	Y
	C.III.1	Y	Y
	C.III.2	Y	N
	C.III.3	Y	N
	C.III.4	Y	N
	C.III.5	Y	N
	C.III.6	Y	Y
	C.III.7	Y	N
	C.III.8	Y	Y
	C.III.9	Y	Y
	C.IV.1	Y	N
Equitable Pricing, Manufacturing and Distribution	D.I.1	N	N
	D.I.2	N	N
	D.I.3	N	Y
	D.I.4	N	Y
	D.I.5	N	Y
	D.I.6	N	N
	D.II.1	Y	Y

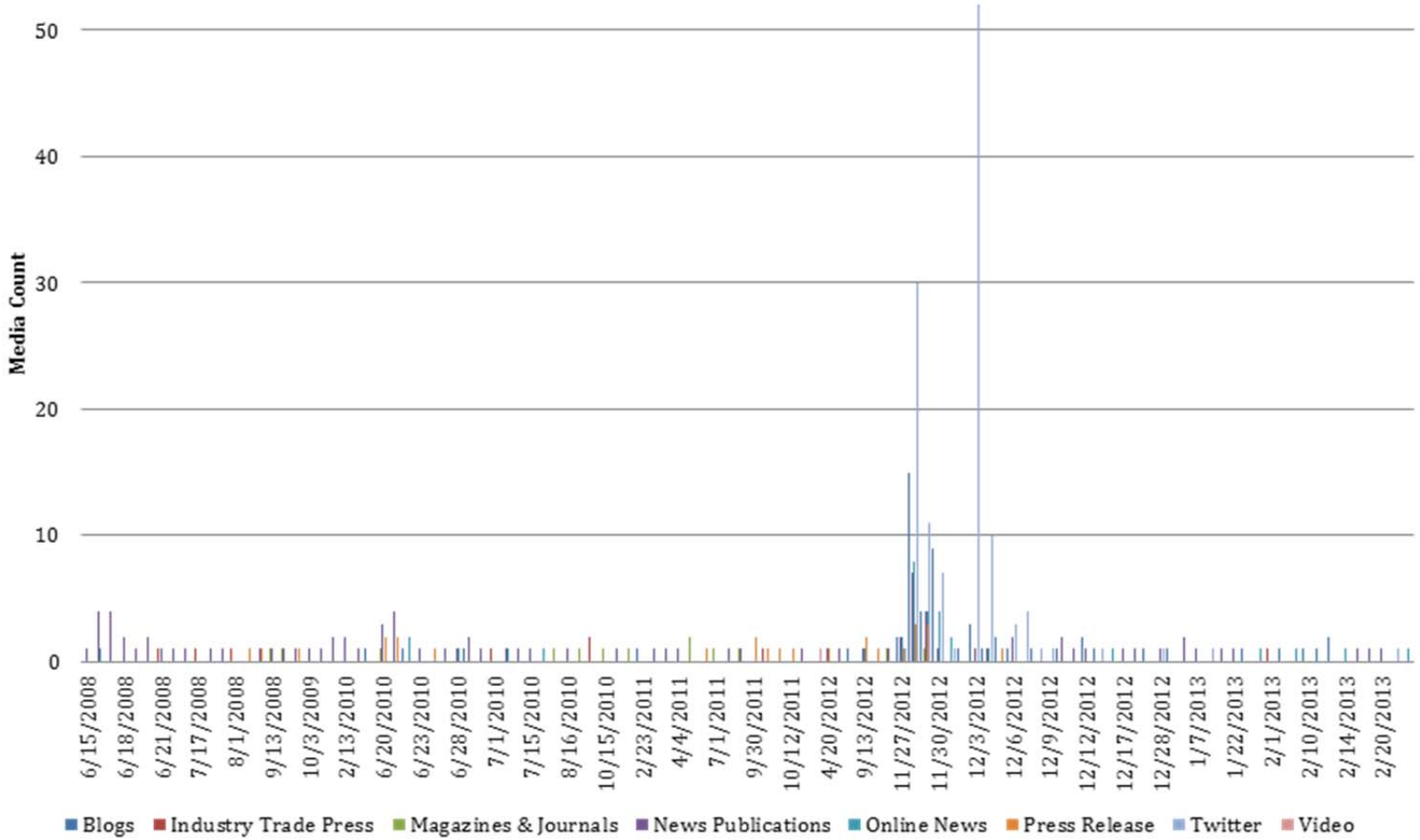
	Indicator	Specific	Data Source
Equitable Pricing, Manufacturing and Distribution	D.II.2	N	Y
	D.II.3	Y	Y
	D.II.4	Y	Y
	D.II.5	Y	Y
	D.III.1	Y	N
	D.III.2	Y	N
	D.III.3	Y	N
	D.III.4	Y	N
	D.III.5	Y	N
	D.III.6	Y	N
	D.IV.1	Y	N
	D.IV.2	Y	N
Patents and Licensing	E.I.1	N	N
	E.I.2	Y	Y
	E.I.3	N	N
	E.I.4	Y	Y
	E.II.1	N	Y
	E.II.2	Y	Y
	E.II.3	N	Y
	E.III.1	Y	N
	E.III.2	Y	N
	E.III.3	Y	Y
	E.III.4	Y	N
	E.III.5	Y	N
	E.IV.1	Y	N
Capability Advancement in Product Development and Distribution	F.I.1	N	N
	F.I.2	Y	N
	F.I.3	Y	Y
	F.I.4	Y	Y
	F.II.1	Y	Y
	F.III.1	Y	N
	F.III.2	Y	N
	F.III.3	Y	N
	F.III.4	Y	N
	F.III.5	Y	Y
	F.IV.1	Y	N
	F.IV.2	Y	N
Product Donations & Philanthropic Activities	G.I.1	N	N
	G.I.2	N	N
	G.I.3	N	N
	G.I.4	N	N
	G.II.1	Y	Y
	G.II.2	Y	Y
	G.II.3	N	Y
	G.III.1	N	Y
	G.III.2	N	N
	G.III.3	Y	N
	G.III.4	N	Y
	G.IV.1	Y	N
	G.IV.2	Y	N

xix. Count of Media Reports Containing "Access to Medicine Index" Excluding Social Media



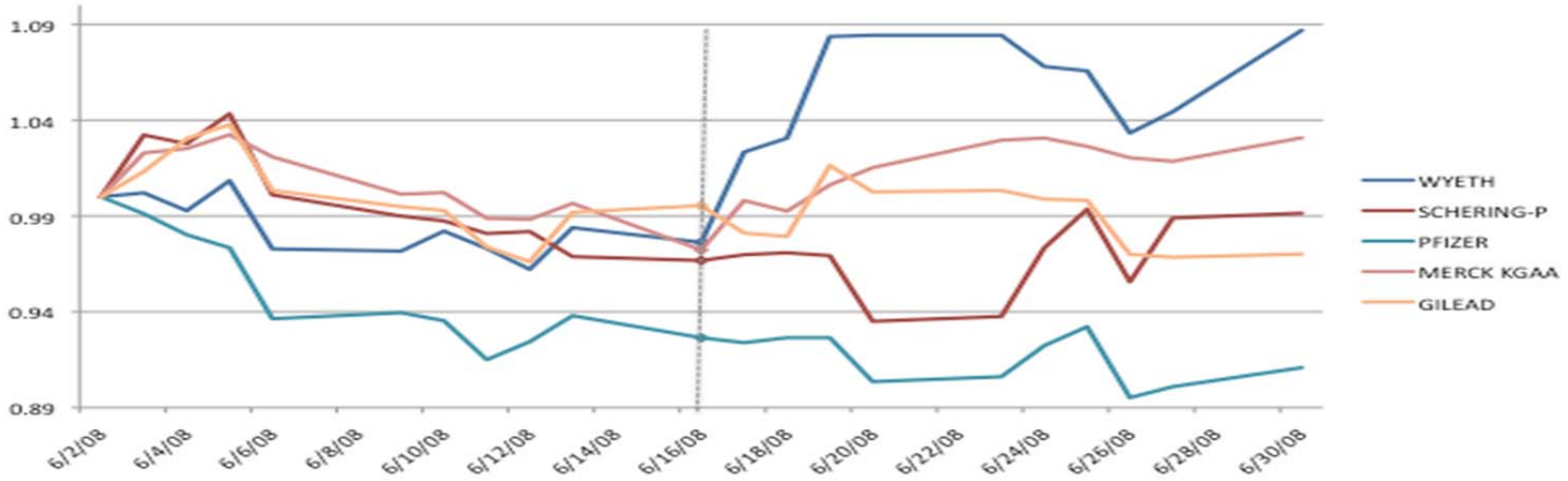
*Note: Media count was based on analysis of all news from all sources for all date ranges based on the term "Access to Medicine Index" in Factiva, Lexis / Nexis, ABI / Inform Complete and Business Source Complete, accessed on March 3-4, 2013. Identical duplicates were eliminated when title, date and source matched.

xx. Count of Media Reports Containing "Access to Medicine Index" Including Social Media

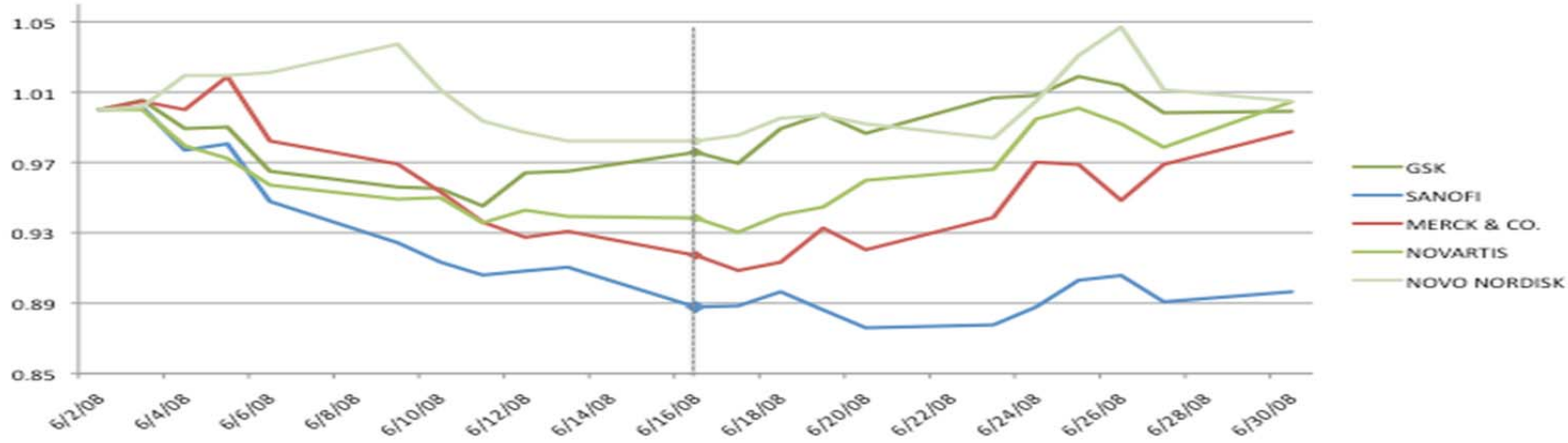


*Note: Media count was based on analysis of all news from all sources for all date ranges based on the term "Access to Medicine Index" in Factiva, Lexis / Nexis, ABI / Inform Complete and Business Source Complete, accessed on March 3-4, 2013. Identical duplicates were eliminated when title, date and source matched.

xxi. Indexed share price movements of 2008 ATMi 5 worst performers (6/16/08 release)



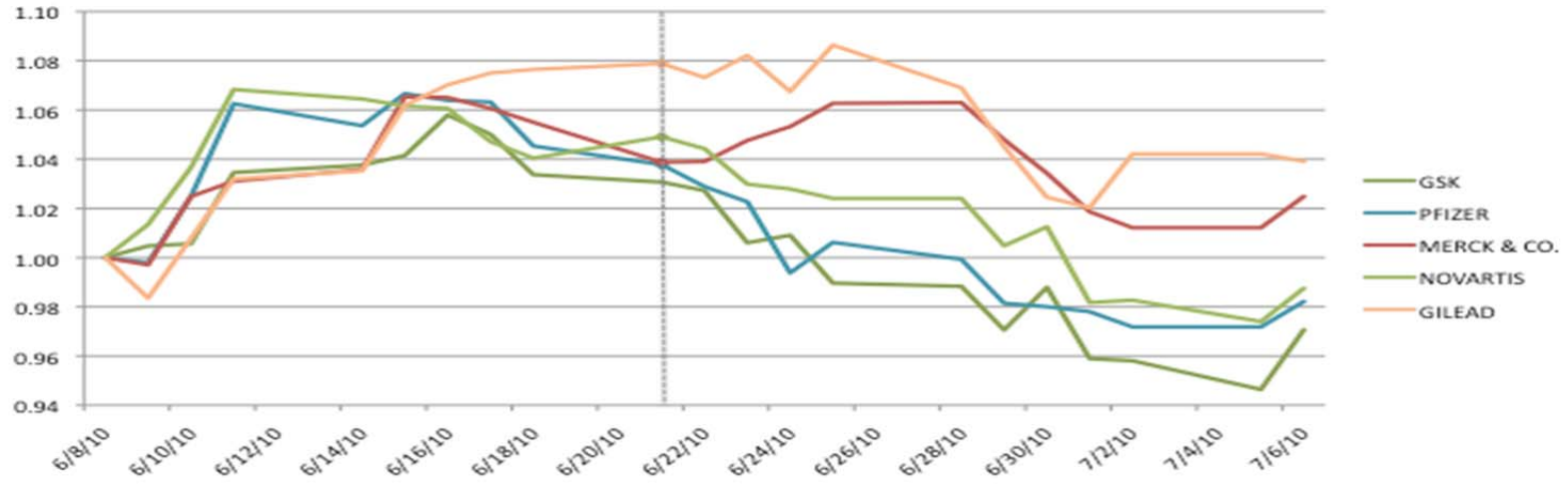
xxii. Indexed share price movements of 2008 ATMi 5 best performers (6/16/08 release)



Source: Bloomberg Professional accessed on February 11, 2013

xxiii. Indexed share price movements of 2010 ATMi 3 worst performers and 2 worst decreases (6/21/10 release)

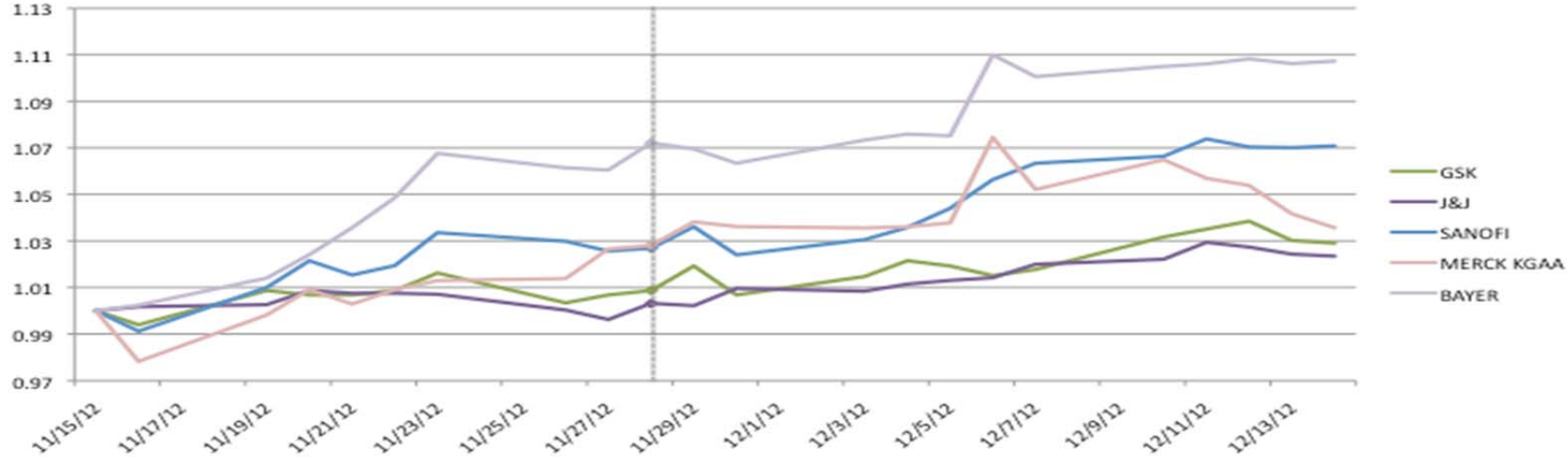
xxiv. Indexed share price movements of 2010 ATMi 3 best performers and 2 best improvers (6/21/10 release)



Source: Bloomberg Professional accessed on February 11, 2013

xxv. Indexed share price movements of 2012 ATMi 3 worst performers and 2 worst decreases (11/28/12 release)

xxvi. Indexed share price movements of 2012 ATMi 3 best performers and 2 best improvers (11/28/12 release)



Source: Bloomberg Professional accessed on February 11, 2013

xxvii. Analysis of civil sector public recognition of ATMi results (as of 2/10/13)

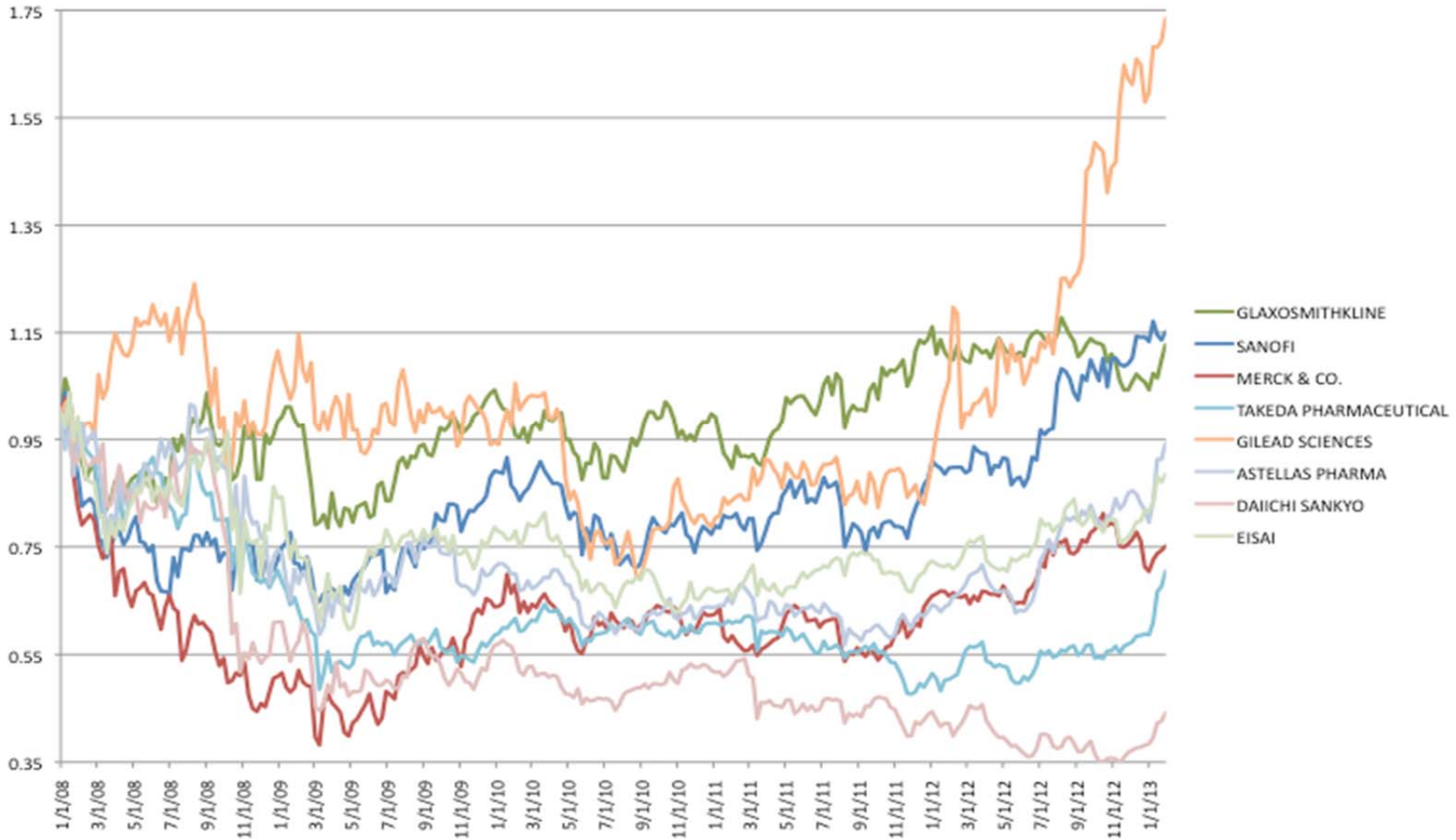
Organization	2010 Index Link on Website	2012 Index Link on Website	Analysis of ATMi Results on Website
World Health Organization (WHO)	Yes – 11/12	Yes – 11/12	No
GAVI	No	No	No
The Global Fund	No	No	No
UNAIDS	No	No	No
UNICEF	No	No	No
Médecins Sans Frontières	No	No	No
Health Action International	No	No	Yes – 6/08 (Critique)
Oxfam	Yes	No	Yes – 2010 only
Department for International Development	Yes	No	No
Clinton Health Access Initiative	No	No	No
The Bill & Melinda Gates Foundation	Yes	No	No
UNITAID	No	No	No
UNDP	No	No	No
Knowledge Ecology International	No	No	No
Pan American Health Organization	No	No	Y - Reference to BBC article 11/12
Drugs for Neglected Diseases Initiative	No	No	No
Human Rights Watch	No	No	No
Treatment Action Campaign (TAC)	No	No	No
Section 27	No	No	No
Lawyers Collective	No	No	No
Thai AIDS Treatment Action Group (TTAG)	No	No	No
Conectas Direitos Humanos	No	No	No
Justiça Global	No	No	No
Paz y Esperanza (Peace and Hope)	No	No	No
Asian Human Rights Commission	No	No	No
Global Rights	No	No	No

xxviii. Analysis of private sector recognition of ATMi results and ranking (as of 2/10/13)

Rank		Organization	2010 Index Referenced in 2011/2010 CSR / Annual Report	2012 Index Link on Website	Analysis of 2012 ATMi Results on Website
2012	2010				
1	1	GlaxoSmithKline plc	Yes	Yes	Y – Press release on 11/12 with response by CEO
2	9	Johnson & Johnson	No	Yes	Y – Statement on 11/12 with response by VP, Global Market Access
3	5	Sanofi	No	Yes	Y – Statement on 11/12 with response by VP, CSR
4	2	Merck & Co	Yes	No - only link to index, not results	No
5	4	Gilead Sciences	No	No	No
6	8	Novo Nordisk A/S	No	Yes	Yes – Statement on 11/12 by VP, Global Stakeholder Engagement
7	3	Novartis AG	No	No	No – Ranking result noted for 2012 on website
8	17	Merck KGaA	No - Index recognized but not result	Yes	Yes – Press release on 11/12 by Executive Board Member of Merck and Head of the Merck Serono
9	14	Bayer AG	No - Index recognized but not result	Yes	Yes – website statement on 11/12
10	6	Roche Holding Ltd	No	No	No
11	11	Pfizer Inc	No	No – only acknowledgement of index	No
12	15	Bristol-Myers Squibb Co	No	No	No
13	10	Abbott Laboratories Inc	No	No	No
14	13	Eli Lilly & Co.	No	No	No
15	16	Eisai Co Ltd	No	No	No
16	7	AstraZenca Plc	No - Index recognized but not result	No – details 2010 results	No

Rank		Organization	2010 Index Referenced in 2011/2010 CSR / Annual Report	2012 Index Link on Website	Analysis of 2012 ATMi Results on Website
2012	2010				
17	12	Boehringer-Ingelheim	Yes	No	No
18	18	Takeda Pharmaceutical Co.	No	No	No
19	20	Daiichi Sankyo Co. Ltd.	No	No	No
20	19	Astellas Pharma Inc.	No	No	No

xxix. Indexed share price movements of top 4 and worst 4 ATMi performers since 2008



Note: Top performers since 2008 of ATMi include GSK, Sanofi, Merck & Co and Gilead Sciences.
Worst performers since 2008 of ATMi include Takeda, Astellas, Daiichi and Eisai.
Source: Bloomberg Professional accessed on February 11, 2013

xxx. Analysis of Changes in Company Performance from 2010 to 2012

The following information has been sourced directly from the Access to Medicine Index 2012 report. Positive developments have been noted in black while negative developments have been noted in red. Lack of discernible action is noted by blank cells.

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
1	**1**	**GlaxoSmithKline plc**	- Created Developing Countries and Market Access (DCMA) unit centralizing LDC business units, aligned incentives with volume growth. - Sponsored > 30 access related conferences and workshops	- Introduced more advanced ethical marketing codes of conduct with standards that exceed IFPMA marketing code.	- Larger R&D pipeline for new medicines and adaptive research for the poor. - Established Tres Cantos Open Lab Foundation with initial donation of USD 1.9 million to focus on projects for the developing world, with treatments for neglected diseases developed to be made available royalty free to LDCs.	- Product quality recalls due to quality issues. - Introduced inter-country tiered pricing for 32 and intra-country tiered pricing for seven out of 33 products in several relevant countries. - Six ethical breaches; sale of unregistered pharmaceutical products to improper product advertising. 2012 fine of USD 3 billion for misleading promotion of range of drugs including rosiglitazone (Avandia®) for period 1997 to 2004. - Pleaded guilty in 2011 to unlawfully promoting two antidepressant drugs (Paxil® and Wellbutrin®) for unapproved uses in US.	- Issued NEVLs for HIV medicine only through GSK-Pfizer joint initiative, ViiV. -Entered in negotiations with Medicines Patent Pool through ViiV.	- Broad range of examples disclosed of building pharmacovigilance systems in multiple relevant countries.	- Dedicated 20% profits from LDCs to strengthen health care infrastructure in LDCs (USD 6 million in 2011).

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
2	**9**	**Johnson & Johnson**	- Consolidated access activities to one business unit, the Global Pharmaceutical Access Committee within Janssen pharmaceutical business and with board-level involvement.	- Improved transparency and more explicit codes of conduct. - April 2011 SEC kickbacks to Iraqi authorities to secure 19 contracts in UN Oil for Food Program.	- Acquisition of Crucell, increased pipeline dedicated to innovation in 13 relevant diseases and adaption of products for seven relevant diseases.	- Increased disclosure of tiered pricing programs	- Greater public transparency towards TRIPS flexibilities. - Public disclosure of limited range of patent statuses. - Issued non-exclusive voluntary licenses for all three of its HIV/AIDS products and engaged in related technology transfer. - Withdrew from Medicines Patent Pool formal negotiations in December 2011. - Public acceptance of practice of compulsory licensing, but only as a last resort. - Commits not to enforce patents in UN LDCs related to index diseases.	- Broad range of examples disclosed of building pharmacovigilance systems in multiple relevant countries.	

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
							- Commenced issuing NEVLs for three of its HIV products, however one doesn't cover manufacturing and the other is limited to India.		
3	**5**	**Sanofi**	- Hosted > 200 access related workshops and meetings. - Established Asia-Pacific Therapeutic Strategic Unit and specific research and development unit focusing on communicable diseases.		- Introduced adaptive product research.	- Rolled out intra-country tiered pricing for large number of countries but for limited products.	- Greater disclosure of positions on TRIPS and enforcement and filing of patents in LDCs. - Commits not to file or enforce patents in LDCs		- Sanofi Espoir Foundation established in late 2010, committed in 2011 US 10.7 supporting 15 access-orientated projects and two single-drug donation programs targeting trypanasomiasis.
4	**2**	**Merck & Co**			-Started Merck for Mothers Initiative to prevent hemorrhage and pre-eclampsia and to focus on family planning.		- Granted four NEVLs over last two years for its HIV/AIDS and diabetes products. - Will not assert patent for Efavirenz/ Stocrin® in South Africa		

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
							- Lobbying relevant country governments such as Indonesia and Philippines for stronger intellectual property protection.		
5	**4**	**Gilead Sciences**		- Has better standards for bribery and corruption			- Engaged with Medicines Patent Pool - Increasing use of non-exclusive voluntary licenses. - Issued NEVLs for two ARVs Viread® and Truvada®.		- Commenced single drug donation program to treat visceral leishmaniasis in addition to not-for-profit pricing arrangements in India.
6	**8**	**Novo Nordisk A/S**		- Access orientated policy commitments - Full commitment to not apply data exclusivity	- Increased R&D adaptive pipeline.			- Changing Diabetes in Children program provides integrated community support.	- Introduced single-drug donation program for non-patented human insulin in Sub-Saharan Africa.

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
7	**3**	**Novartis AG**		- Implemented third-party auditing and enforcement mechanisms.	- Increased R&D adaptive pipeline.		- Contesting decision by Indian Government over application and TRIPS compatibility of patentability criteria.		
8	**17**	**Merck KGaA**	- Developed access to medicine charter with board-level responsibility.		- Commenced investment in innovative and adaptive R&D for poor	- First time disclosure of tiered pricing program.		- Minilabs initiative in collaboration with Global Pharma Health Fund allows for rapid field-based detection of potentially substandard medicines covering 58 drug compounds, most on WHO EML.	- Greater disclosure
9	**14**	**Bayer AG**	- Publishing more information on access acivities, including targets and performance.			- Introduced intra-country four-tiered differential pricing scheme.	- Greater disclosure of positions on TRIPS and enforcement and filing of patents in LDCs. - Contesting decision by Indian Government over compulsory license for cancer		

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
							medication.		
10	**6**	**Roche Holding Ltd**			- Increased R&D adaptive pipeline, but has no relevant innovative molecules.		-Entered in negotiations with Medicines Patent Pool.		
11	**11**	**Pfizer Inc**			- Out of court settlement in 2011 for clinical trial regulatory breach in Nigeria of meningitis antibiotic Trovan® in 1996.	- Implemented tiered pricing for all relevant products in every country where present.	-Entered in negotiations with Medicines Patent Pool through ViiV.		
12	**15**	**Bristol-Myers Squibb Co**		- Improved transparency and has more explicit codes of conduct.			-Entered in negotiations with Medicines Patent Pool.		
13	**10**	**Abbott Laboratories Inc**				- Acquired in 2010 Solvay Pharmaceuticals and the Healthcare Solutions division of Piramal Healthcare Ltd, branded generic manufacturer. - Noted evidence of		- Increased investment in capacity building for R&D, including diagnostic and treatment service in Western Kenya	

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
						litigation and regulatory proceedings regarding patents and the application of TRIPS flexibilities, but no details provided.		and healthcare public-private partnership with Tanzanian government.	
14	**13**	**Eli Lilly & Co.**		- Improved transparency and more explicit codes of conduct.	- Commenced investment in innovative R&D for poor. - Subject of several legal cases relating to clinical trials resulting in negative rulings or regulatory notices. - New Open Innovation Drug Discovery program, a web-based tool to allow external researchers to register molecules.				
15	**16**	**Eisai Co Ltd**	- Dedicated Global Access Strategies unit and board ownership of access. Created a management system to track and reward progress on	- Has better standards for bribery and corruption	- Improved investment in research in NTD	-Introduced tiered pricing for breast cancer drugs and introduced affordable pricing schemes for epilepsy and unipolar depressive disorder drugs in India.	- Lack of evidence of follow through of NEVL commitments		- Introduced single drug donation program for NTD (2010) to treat lymphatic filariasis in developing countries, beginning in 2013.

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
			access related initiatives.						
16	**7**	**AstraZenca Plc**				- Product recalls - Committed only to intra-country tiered pricing with schemes outside the scope of the index. - Established manufacturing plants in China and Algeria - 28 marketing and sales breaches during 2010-11.	-Reneged on commitment to not to file or enforce patents in LDCs, where there is a good market.	- Provided research capacity support to Peking University for a Clinical Pharmacology Unit and participated in More Medicines for Tuberculosis consortium and Medicines for Malaria Venture.	- New program to support improved health and lifestyle choices for adolescents in India and Zambia.
17	**12**	**Boehringer-Ingelheim**			- Expanded R&D pipeline for relevant diseases such as asthma, cerebrovascular disease, diabetes mellitus and malaria.	- Fined in Ukraine in 2010 for false claims about a drug.	- Significantly increased number (from 6 to 14) of non-assert declarations for its anti-retroviral. -Entered in negotiations with Medicines Patent Pool.	- Making More Health launched to support social entrepreneurs to advance sustainable health solutions across developing countries.	
18	**18**	**Takeda Pharmaceutical Co.**			- Added two new molecules for unipolar depressive disorder and invested in adaptive research to explore effects of tropical climates on its	- Acquired generics manufacturer Nycomed, increasing present in relevant markets and expanding vaccine division, including work on polio virus vaccine. - Improved anti-counterfeiting program.		- Introduced new quality assurance framework to analyze seized drug samples.	- Greater alignment with Millennium Development Goals, including improving child health and prevention of HIV/AIDS.

2012	2010	Co.	Commitments / Engagement	Public Policy	R&D	Pricing, Manufacturing & Distribution	Patents & Licensing	Capability Advancement	Donations & Philanthropy
					products.				
19	**20**	**Daiichi Sankyo Co. Ltd.**			-Acquired generics manufacturer Ranbaxy; added six relevant products for in scope diseases: nephritis, cirrhosis of the liver, meningitis, ischaemic heart disease, trachoma and maternal health conditions.	-Implemented tiered pricing schemes covering more than half of its relevant products, though in limited markets, inter-country tiered pricing for four of 17 relevant products and intra-country tiered pricing for nine out of 17 relevant products.			
20	**19**	**Astellas Pharma Inc.**			- New R&D collaboration with Drugs for Neglected Diseases initiative for three NTD and a public-private partnership with TI Pharma, Merck KGaA and Swiss TPH to develop pediatric form of Praziquantel to treat schistosomiasis.		- Lack of evidence of follow through of NEVL commitments		

xxxi. Analysis of Different Benchmarking Approaches of the Pharmaceutical Sector

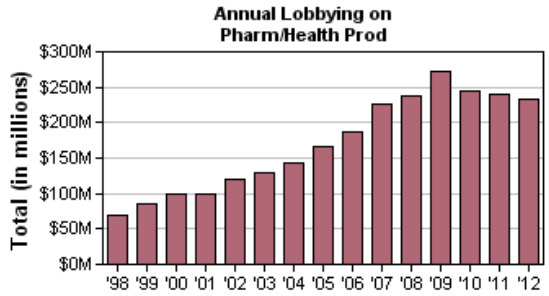
Index	Title	Year	Frequency	Theme Scope	Company Scope	Research Methodology	Scoring Methodology	Number of Indicators	Indicator Scores By Company	Company Profiles Published	Leading Pharmaceutical Companies	Worst Pharmaceutical Companies
CoreRatings	Pharmaceutical Sector: Philanthropy or Good Business?	2003	Once	Policy, practice and disclosure in management of emerging market responsibilities	11 largest international pharmaceutical companies by market capitalization	Company survey	6 possible scores per indicator.	5; equal weighting applied	Yes	Yes	GSK (#1), Novartis (#2), Merck (#3) and Roche (#4)	Eli Lily (#10), Abbot (#9), Pfizer (#8) and Johnson and Johnson (#7)
Interfaith Center on Corporate Responsibility	Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Countries	2006	Once	HIV/AIDS and neglected diseases in Emerging Markets	15 pharmaceutical companies addressing at least one of HIV/AIDS, TB or Malaria.	Company survey, direct verbal and written communications and expert committee review.	5 point scale	12; equal weighting applied	Yes	Yes	Ranking only by theme, not overall.	Ranking only by theme, not overall.

Index	Title	Year	Frequency	Theme Scope	Company Scope	Research Methodology	Scoring Methodology	Number of Indicators	Indicator Scores By Company	Company Profiles Published	Leading Pharmaceutical Companies	Worst Pharmaceutical Companies
Oxfam International	Investing for Life: Meeting Poor People's Needs for Access to Medicines Through Responsible Business Practices	2007	Once	Access to essential medicines; pricing, R&D and patents	12 pharmaceutical companies in terms of market capitalization and 1 biotechnology company due its product portfolio	Company interviews and publicly available data	None noted, observations aligned to HBR CSR spectrum.	None noted	Not applicable	Yes	Ranking only by theme, not overall.	Ranking only by theme, not overall.
Pacific Sustainability Index	Sustainability Reporting of the World's Largest Pharmaceutical Companies	2009	Once	Environmental and social sustainability reporting and transparency	Companies on Fortune Global 500 and Fortune 500 Pharmaceuticals sector lists (up to 30)	Review of websites and direct verbal and written communications.	Three points for qualitative topics, five points for quantitative topics and 7 points for human rights topics.	Not detailed	No	Yes	Bristol-Myers Squibb (#1), Sanofi (#2), Abbott (#3) and Johnson & Johnson (4)	Gilead Sciences (#18), Eli Lilly (#16), Novartis (#13) and Pfizer (#11)

Index	Title	Year	Frequency	Theme Scope	Company Scope	Research Methodology	Scoring Methodology	Number of Indicators	Indicator Scores By Company	Company Profiles Published	Leading Pharmaceutical Companies	Worst Pharmaceutical Companies
Justmeans Insights	Sustainable Performance Leaders in Pharmaceuticals	2010	Annual	Environment, social and governance.	Publicly traded company on a major global exchange, minimum market capitalization of $1 Billion USD and must have published CSR report.	CSR reports and direct verbal and written communications, and government filings; must be publicly available	Proprietary and not detailed. Consists of numeric or Boolean (Yes or No)	175	Detailed information only accessible by subscribers	Yes	Roche (#2), Astrazenca (#3), Merck & Company (#4) and Abbott (#5)	Eisai (#24), Eli Lilly (#23), Astellas (#21), and Takeda (#20).
PatientView	The Corporate Reputation of Pharma in 2012 – the Patient Perspective	2012	Annual	Extent to which pharmaceutical companies are meeting the expectations of patients and patient groups	29 leading pharmaceutical companies	Survey 600 international, national, regional and local patient groups for opinions (European bias). Minimum of 25 completed responses per company required for inclusion.	Yes	6	Only accessible for fee; Yes	Only accessible for fee; Yes.	Gilead Sciences (#2), Novartis (#3), Pfizer (#5) and Abbott (#6)	Only accessible for fee.

Index	Title	Year	Frequency	Theme Scope	Company Scope	Research Methodology	Scoring Methodology	Number of Indicators	Indicator Scores By Company	Company Profiles Published	Leading Pharmaceutical Companies	Worst Pharmaceutical Companies
CPA-Zicklin	2012 CPA-Zicklin Index of Corporate Political Accountability and Disclosure	2012	Annual	Board oversight and disclosure of direct and indirect political spend	Top 200 companies, as measured by market capitalization at the end of 2011, in the S&P 500	Review of websites and direct verbal and written communications.	Yes = Full points; No = 0 points; Partial = Half points.	29; with indicators having different point weights	Yes	No	Merck & Co (#1), Gilead Sciences (#4), Johnson & Johnson (#11) and Pfizer (#12)	Eli Lily & Company (#40), Bristol-Myers (#29) and Abbott Laboratories (#20)

xxxii. Pharmaceutical Industry Lobbying Profile, 2012



Client/Parent	Total
Pharmaceutical Rsrch & Mfrs of America	$18,530,000
Eli Lilly & Co	$11,096,000
Pfizer Inc	$10,210,000
Merck & Co	$9,510,000
Amgen Inc	$9,310,000
Biotechnology Industry Organization	$7,540,000
Novartis AG	$7,367,000
Abbott Laboratories	$6,200,000
Sanofi	$6,174,000
Johnson & Johnson	$5,880,000
Bayer AG	$5,800,321
Roche Holdings	$5,320,846
GlaxoSmithKline	$4,920,000
Medtronic Inc	$4,900,000
AstraZeneca PLC	$3,570,000
Bristol-Myers Squibb	$3,320,000
Merck KGaA	$3,050,000
Teva Pharmaceutical Industries	$3,040,000
CH Boehringer Sohn	$2,940,618
Baxter International	$2,590,000
Eisai Co Ltd	$2,410,000
Novo Nordisk Pharmaceuticals	$2,240,000
Astellas Pharma USA	$2,220,000
Cardinal Health	$2,165,000
Pharmaceutical Care Management Assn	$2,118,253

Source: Center for Responsive Politics (Accessed March 12, 2013)

xxxiii. Gilead Sciences Product Portfolio and Research Pipeline

Note: Cells denoted in yellow are specifically referenced in the analysis of the report. All product and pipeline information obtained from Gilead website in February 2013.

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PRODUCTS													
HIV/AIDS	Viread® (tenofovir disoproxil fumarate)	Y	Y			Y	Y	Y		Y	103		
HIV/AIDS	Truvada® (emtricitabine/ tenofovir disoproxil fumarate)	Y	Y			Y		Y		Y	100		
HIV/AIDS	Atripla® (efavirenz/ emtricitabine/ tenofovir disoproxil fumarate)	Y	Y										
HIV/AIDS	Complera® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)	N	N										
HIV/AIDS	Emtriva® (emtricitabine)	Y	Y				Y						
HIV/AIDS	Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg)	Y	N			Y	Y						
Leishmaniasis	AmBisome® (amphotericin B)	Y	Y	Y	50,000								
Cystic Fibrosis	Cayston® (aztreonam for inhalation solution)	N	N										
Influenza infection	Tamiflu® (oseltamivir phosphate)	N	Y										
Liver disease (Hepatitis B)	Hepsera® (adefovir dipivoxil)	N	N										
Liver disease (Hepatitis B)	Viread® (tenofovir disoproxil fumarate)	Y	Y			Y	Y	Y			54		
Macular degeneration	Macugen® (pegaptanib sodium injection)	N	N										
Cytomegalovirus retinitis (HIV/AIDS)	Vistide® (cidofovir injection)	N	N										
Pulmonary arterial hypertension	Letairis® (ambrisentan)	N	N										
Radionuclide myocardial perfusion imaging	Lexiscan® (regadenoson)	N	N										
Chronic angina	Ranexa® (ranolazine extended-release tablets)	N	N										

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PIPELINE													
HIV/AIDS	"Quad" Integrase STR (elvitegravir/FTC/TDF/cobicistat)	Y	N/A				Y						EU Approval Submitted
HIV/AIDS	Elvitegravir (integrase inhibitor)	Y	N/A			Y	Y						U.S. and EU Approvals Submitted
HIV/AIDS	Cobicistat (formerly GS-9350) (PK enhancer)	Y	N/A			Y	Y						U.S. and EU Approvals Submitted
HIV/AIDS	GS-7340 (nucleotide reverse transcriptase inhibitor)	Y	N/A										Phase 2
Hepatitis C	GS-7977 (nucleotide NS5B inhibitor)	N	N/A										Phase 3
Hepatitis C	GS-5885 (NS5A inhibitor)	N	N/A										Phase 3
Liver Fibrosis	GS-6624 (monoclonal antibody)	N	N/A										Phase 2
Hepatitis C	Tegobuvir/GS-9190 (non-nucleoside NS5B inhibitor)	N	N/A										Phase 2
Hepatitis C	GS-9256 (NS3 protease inhibitor)	N	N/A										Phase 2
Hepatitis C	GS-9451 (NS3 protease inhibitor)	N	N/A										Phase 2
Hepatitis C	GS-9669 (non-nucleoside polymerase inhibitor)	N	N/A										Phase 2
Hepatitis C / Hepatitis B	GS-9620 (TLR-7 agonist)	N	N/A										Phase 1
Hepatitis B	GS-7340 (nucleoside reverse transcriptase inhibitor)	N	N/A										Phase 1
Incomplete Revascularization Post-PCI	Ranolazine (late sodium current inhibitor)	N	N/A										Phase 3
Type 2 Diabetes	Ranolazine (late sodium current inhibitor)	N	N/A										Phase 3
Paroxysmal Atrial Fibrillation	Ranolazine/Dronedarone Fixed-Dose Combination	N	N/A										Phase 2
Bronchiectasis	Aztreonam for Inhalation Solution	N	N/A										Phase 3
Idiopathic Pulmonary Fibrosis	GS-6624 (monoclonal antibody)	N	N/A										Phase 1
Respiratory Syncytial Virus	GS-5806	N	N/A										Phase 1
Chronic Lymphocytic Leukemia	GS-1101 (PI3K delta inhibitor)	N	N/A										Phase 3
Indolent non-Hodgkin's Lymphoma	GS-1101 (PI3K delta inhibitor)	N	N/A										Phase 2
Colorectal Cancer	GS-6624 (monoclonal antibody)	N	N/A										Phase 2
Myelofibrosis	GS-6624 (monoclonal antibody)	N	N/A										Phase 2
Pancreatic Cancer	GS-6624 (monoclonal antibody)	N	N/A										Phase 2

xxxiv. Sanofi Product Portfolio and Research Pipeline

Note: Cells denoted in yellow are specifically referenced in the analysis of the report. All product and pipeline information obtained from Sanofi website in February 2013.

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PRODUCTS													
Diabetes	Lantus® (insulin glargine)	Y	N										
Diabetes	Apidra® (insulin glulisine)	Y	N										
Diabetes	Insuman®	Y	N										
Diabetes	Amaryl®/Amarel® (glimepiride)	Y	N										
Diabetes	SoloSTAR® injection pens	Y	N										
Diabetes	ClikSTAR®, a reusable pen for Lantus® and Apidra®	Y	N										
Oncology	Taxotere® (docetaxel)	N	Y										
Oncology	Eloxatin® (oxaliplatin)	N	N										
Oncology	Jevtana® (cabazitaxel)	N	N										
Pediatric combination vaccines	Pentacel® (DTaP-IPV/Hib)	N	Y										
Pediatric combination vaccines	Pediacel® (DTaP(5)-IPV-Hib)	N	Y										
Pediatric combination vaccines	Act-HIB® (Haemophilus b Conjugate Vaccine)	N	Y										
Pediatric combination vaccines	Pentaxim™	N	Y										
Pediatric combination vaccines	Tetraxim™ (DTacP-IPV)	N	Y										
Poliomyelitis (polio) vaccine	Imovax™ Polio (inactivated poliomyelitis vaccine)	N	Y										
Influenza vaccines	Fluzone® (Influenza Virus Vaccine)	N	Y										
Influenza vaccines	Vaxigrip®/Mutagrip®	N	Y										
Influenza vaccines	Intanza®/IDflu®	N	Y										
Influenza vaccines	Panenza® (H1N1)	N	Y										
Influenza vaccines	Humenza® (H1N1)	N	Y										
Polio booster vaccine	Adacel® (TDap)	N	N										
Polio booster vaccine	Quadracel® (DTap-IPV)	N	N										
Meningitis and pneumonia vaccines	Menactra® (Polysaccharide Diphtheria Toxoid Conjugate Vaccine)	Y	Y										

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
Travel/endemic vaccines	Hepatitis A, typhoid fever, rabies, yellow fever, cholera, measles, Japanese encephalitis, mumps and measles, antivenin serums	N	Y										
Rare disease - Gaucher	Cerezyme® (imiglucerase for injection)	N	N										
Rare disease - Fabry	Fabrazyme® (agalsidase beta)	N	N										
Rare disease - Pompe	Myozyme® / Lumizyme® (alglucosidase alfa)	N	N										
Pain killer	Doliprane® (acetaminophen)	N	N										
Dietary supplement	Magné B6® (magnesii lactas dihydricus and pyridoxini hydrochloridum)	N	N										
Children diarrhea	Enterogermina® (Bacillus Clausii)	Y	N										
Liver supplement	Essentiale® (polyenylphosphatidylcholine)	N	N										
Antacid	Maalox® (aluminium hydroxide and magnesium hydroxide)	N	N										
Analgesic	No Spa® (drotaverine)	N	N										
Female hygeine	Lactacyd®.	N	N										
Atherothrombosis	Plavix® (clopidogrel bisulfate)	N	N										
Deep vein thrombosis	Lovenox® (enoxaparin sodium)	N	N										
Atrial fibrillation	Multaq® (dronedarone)	N	N										
High blood pressure	Aprovel® (irbesartan)	N	N										
High blood pressure	CoAprovel® (irbesartan hydrochlorothiazide)	N	N										
Chronic kidney disease	Renagel® (sevelamer hydrochloride)	N	N										
Chronic kidney disease	Renvela® (sevelamer carbonate)	N	N										
Osteoarthritis of certain joint	Synvisc® and Synvisc-One® (hylan G-F 20)	N	N										
Insomnia	Stilnox® (zolpidem)	N	N										
Allergy	Allegra®/Telfast® (fexofenadine hydrochloride)	N	N										
High blood pressure, congestive heart failure or kidney disease	Tritace®/Triatec® (ramipril)	N	N										
Epilepsy	Depakine® (sodium valproate)	Y	Y										
Benign prostatic hyperplasia	Xatral® (alfuzosin hydrochloride)	N	N										
Osteoporosis or Paget's disease	Actonel® (risedronate sodium)	N	N										
Hay Fever	Nasacort® (triamcinolone acetonide)	N	N										
African trypanosomiasis	Eflornithine	N	Y										
African trypanosomiasis	Melarsoprol	N	Y										
African trypanosomiasis	Pentamidine	N	Y										
Filariasis	Notezine (Diethylcarbamazine)	N	Y										

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PIPELINE													
Solid tumors	SAR153192 Anti-DLL4 mAb	N	N/A										Phase 1
PTEN - Deficient tumors	SAR260301 PI3K β selective	N	N/A										Phase 1
Crohn's disease & Ulcerative colitis	SAR252067 Anti-LIGHT mAb	N	N/A										Phase 1
Rotavirus oral vaccine	Rotavirus Live Attenuated Tetravalent	N	N/A										Phase 1
Solid tumors	GZ402674 Non - camptothecin topo1 inhibitor	N	N/A										Phase 1
Trauma brain injury	SAR127963 P75 receptor antagonist	N	N/A										Phase 1
Skin manifestation of scleroderma	SAR100842 LPA - 1/LPA – 3	N	N/A										Phase 1
Meningitis & pneumonia vaccine	Streptococcus pneumonia	Y	N/A										Phase 1
Hematological malignancies	SAR650984 Anti - CD38 naked mAb	N	N/A										Phase 1
Gene therapy Parkinson's disease	GZ404477 (AAV - hAADC)	N	N/A										Phase 1
Systemic lupus erythematosus	SAR113244 Anti - CXCRS mAb	N	N/A										Phase 1
Prevention of ventilator - associated pneumonia	Pseudomonas aeruginosa Antibody fragment product	Y	N/A										Phase 1
DS6 positive solid tumors	SAR566658 Maytansin - loaded anti DS6 mAb	N	N/A										Phase 1
Rehabilitation post orthopedic surgery	SAR391786	N	N/A										Phase 1
Fix - Flex / Type 2 diabetes	lixisenatide + Lantus® GLP - 1 agonist + insulin glargine	Y	N/A										Phase 1
Recombinant subunit vaccine	Tuberculosis	N	N/A										Phase 1
Solid tumors	SAR307746 Anti - Ang2 mAb	N	N/A										Phase 1
Alzheimer's disease	SAR228810 Anti- protofibrillar AB mAb	N	N/A										Phase 1
CV - related complications & deaths in diabetic patients	SAR164653 Cathepsin A inhibitor	N	N/A										Phase 1
Wet age - related macular degeneration (AMD)	RetinoStat® Gene therapy	N	N/A										Phase 1
Solid tumors	SAR125844 C-Met kinase inhibitor	N	N/A										Phase 1
Pre -sarcopenia	SAR399063 DHA -GLP + vit D	N	N/A										Phase 1
Niemann - Pick type B	GZ402665 (rhASM)	N	N/A										Phase 1
Stargardt disease	StarGen® Gene therapy	N	N/A										Phase 1
Solid tumors	Combinations SAR245409 / MSC1936369B SAR245408/SAR256212 (MM121)	N	N/A										Phase 1
Pre-sarcopenia	SAR404460 DHA - GPL + Vit D	N	N/A										Phase 1
Fabry Disease	GZ402671 GCS Inhibitor	N	N/A										Phase 1
Age - related macular degeneration (AMD)	GZ402663 (sFLT -01) Gene therapy	N	N/A										Phase 1
Solid tumors and hematological malignancies	SAR405838 (MI - 773) HDM2 / p53 antagonist	N	N/A										Phase 1
Acute ischemic stroke	SAR126119 TAFIa inhibitor	N	N/A										Phase 1
Usher syndrome 1B	UshStat ® Gene therapy	N	N/A										Phase 1
Platinum - resistant ovarian cancer (2L)	iniparib (BSI - 201)	N	N/A										Phase 2
Allergic conjunctivitis	FOV1101 FDC prednisolone/cyclosporine	N	N/A										Phase 2

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
Asthma; Atopic dermatitis	SAR231893 Anti-IL4RαmAb	Y	N/A										Phase 2
B-cell malignancies refractory/relapsed (NHL, ALL)	SAR3419 Maytansin-loaded anti-CD19 mAb	N	N/A										Phase 2
Neuropathic pain, osteoarthritic pain	SAR292833 (GRC15300) TRPV3 antagonist	Y	N/A										Phase 2
Malaria	Ferroquine Antimalarial	Y	N/A										Phase 2
Breast cancer (2L, 3L)	SAR256212 (MM121) anti-ErbB3 mAb	N	N/A										Phase 2
Alzheimer's disease	SAR110894 H3 antagonist	N	N/A										Phase 2
Fibrosis	Fresolimumab TGFβ antagonist	N	N/A										Phase 2
Breast cancer	SAR245408 (XL147) Oral PI3K inhibitor	N	N/A										Phase 2
Osteoarthritis	SAR113945 IKK - β inhibitor	Y	N/A										Phase 2
Malaria	SAR97276 Antimalarial	Y	N/A										Phase 2
Non - Hodgkin lymphoma	SAR245409 (XL765) Oral dual inhibitor of PI3K & mTOR	N	N/A										Phase 2
Conjugate infant vaccine	Meninge ACYW conj. 2nd generation meningococcal	N	N/A										Phase 2
Serious infections	SAR279356 (F598)Anti - PNAG mAb	N	N/A										Phase 2
Incyte (ruxolitinib) resistant/intolerant MF	SAR302503 (TG101348) JAK - 2 inhibitor Polycythemia vera (2L)	N	N/A										Phase 2
Toxoid vaccine	ACAM – Cdiff Clostridium difficile	N	N/A										Phase 2
Inflammatory bowel disease	SAR339658 VLA 2 antagonist	N	N/A										Phase 2
Small cell lung cancer (2L)	Jevtana® (cabazitaxel)	N	N/A										Phase 2
Purified vero rabies vaccine	Rabies VRVg	N	N/A										Phase 2
Idiopathic pulmonary fibrosis	SAR156597 IL4/IL13 Bi - specific mAb	N	N/A										Phase 2
Fixed - Ratio / Type 2 diabetes	lixisenatide + Lantus ® GLP - 1 agonist + insulin glargine	Y	N/A										Phase 2
Gaucher disease	eliglustat tartrate Glucosylceramide synthetase inhibitor	N	N/A										Phase 3
ACS	Otamixaban Direct Xa inhibitor	N	N/A										Phase 3
Diphtheria, tetanus, pertussis & polio vaccine; 4 - 6 y of age	Quadracel®	N	N/A										Phase 3
Squamous NSCLC (1L)	Iniparib (BSI - 201)	N	N/A										Phase 3
Type 1+2 diabetes	Insulin glargine New formulation	Y	N/A										Phase 3
Quadrivalent inactivated influenza vaccine	VaxiGrip ® QIV IM	N	N/A										Phase 3
Myelofibrosis (1L)	SAR302503 (TG101348) JAK - 2 inhibitor	N	N/A										Phase 3
Severe HeFH, U.S.	Kynamro™ (mipomersen) Apolipoprotein B - 100 antisense	N	N/A										Phase 3
Mild -to-severe dengue fever vaccine	Dengue	Y	N/A										Phase 3

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
Metastatic prostate cancer (1L)	Jevtana® (cabazitaxel)	N	N/A										Phase 3
Hypercholesterolemia	SAR236553 Anti –PCSK - 9 mAb	N	N/A										Phase 3
Pediatric hexavalent vaccine	DTP – HepB – Polio - Hib	N	N/A										Phase 3
Pain in hip OA	SYNVISC – ONE ® Medical device	N	N/A										Phase 3
Rheumatoid arthritis	Sarilumab (SAR153191) Anti - IL-6R mAb	N	N/A										Phase 3
Quadrivalent inactivated influenza vaccine Intradermal	Fluzone®QIV ID	N	N/A										Phase 3
Articular cartilage defects	MACI® Cell - based treatment	N	N/A										Phase 3
DTP – HepB – Polio - Hib vaccine	Hexaxim ™ / New hexavalent vaccine	N	N/A										Registration
Quadrivalent inactivated influenza vaccine	Fluzone® QIV IM	N	N/A										Registration
(RMS) - Monotherapy, EU	Aubagio® (teriflunomide) Relapsing forms of Multiple sclerosis	N	N/A										Registration
Multiple sclerosis, EU, U.S	Lemtrada™ (alemtuzumab) Anti - CD52 mAb	N	N/A										Registration
Dry syrup, Japan	Allegra®fexofenadine	N	N/A										Registration
HoFH and severe HeFH, EU	Kynamro™ (mipomersen) Apolipoprotein B - 100 antisense	N	N/A										Registration
Type 2 diabetes, U.S., Japan	Lyxumia ® (lixisenatide) GLP -1 agonist	Y	N/A										Registration

xxxv. Novo Nordisk A/S Product Portfolio and Research Pipeline

Note: Cells denoted in yellow are specifically referenced in the analysis of the report. All product and pipeline information obtained from Novo Nordisk website in February 2013.

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PRODUCTS													
Diabetes mellitus	NovoLog® Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin])	Y	Y										
Diabetes mellitus	NovoLog® (insulin aspart [rDNA origin] injection)	Y	Y										
Diabetes mellitus	Levemir® (insulin detemir [rDNA origin] injection)	Y	Y										
Diabetes mellitus	FlexPen® and NovoFine® insulin pens	N	N										
Diabetes mellitus	Prandin (repaglinide tablets)	N	N										
Diabetes mellitus	GlucaGen® HypoKit® (glucagon [rDNA origin] for injection)	Y	Y										
Diabetes mellitus	Victoza (liraglutide [rDNA origin] injection)	N	N										
Hemophilia	NovoSeven® RT (Coagulation Factor VIIa [Recombinant] Room Temperature Stable)	N	Y										
Growth-hormone related disorders	Norditropin® (somatropin [rDNA origin] injection)	N	N										
Estrogen deficiency	Vagifem® (estradiol vaginal tablets)	N	N										
Vasomotor symptoms	Activella® ([estradiol/norethindrone acetate] tablets)	N	N										

Category	Drug compound	In AMI	In WHO EML	Single-Drug Donation Program	# People Doantion Treated	Medicnes Patent Pool	Non-Exclusive Voluntary License	Inter-Country Tiered Pricing	Intra-Country Tiered Pricing	Tiered Pricing Published	# Countries Registered With Tiered Pricing	# Peope Treated in Relevant Countries	Status
PIPELINE													
Type 1 and 2 diabetes	Tresiba® (insulin degludec) (NN1250)	Y	N/A										Registration
Type 1 and 2 diabetes	Ryzodeg® (insulin degludec and insulin	Y	N/A										Registration
FXIII Congenital deficiency	NovoThirteen® (rFXIII) (NN1841)	N	N/A										Registration
Haemophilia A	Turoctocog alfa (NN7008)	N	N/A										Registration
Type 2 diabetes	IDegLira (NN9068)	Y	N/A										Phase 3
Haemophilia A	N8-GP (NN7088)	N	N/A										Phase 3
Haemophilia B	N9-GP (NN7999)	N	N/A										Phase 3
Obesity	Liraglutide 3 mg (NN8022)	N	N/A										Phase 3
Type 2 diabetes	Semaglutide (NN9535)	Y	N/A										Phase 2
Inflammation - Rheumatoid arthritis	Anti-IL20 (NN8226)	N	N/A										Phase 2
Inflammation - Ulcerative colitis	rFXIII (NN8717)	N	N/A										Phase 2
Inflammation - Rheumatoid arthritis	Anti-IL21 (NN8828)	N	N/A										Phase 2
Type 1 diabetes	LATIN T1D (NN9211)	Y	N/A										Phase 1
Type 1 and 2 diabetes	OI338GT (NN1953)	Y	N/A										Phase 1
Type 1 and 2 diabetes	OI362GT (NN1954)	Y	N/A										Phase 1
Type 2 diabetes	OG217SC (NN9924)	Y	N/A										Phase 1
Type 2 diabetes	OG987GT (NN9926)	Y	N/A										Phase 1
Type 2 diabetes	OG987SC (NN9927)	Y	N/A										Phase 1
Type 1 and 2 diabetes	FIAsp (NN1218)	Y	N/A										Phase 1
Type 1 and 2 diabetes	LAI287 (NN1436)	Y	N/A										Phase 1
Haemophilia A and B	mAb2021 (NN7415)	N	N/A										Phase 1
Growth disorder	NN8640	N	N/A										Phase 1
Inflammation - Systemic lupus	Anti-IL21 (NN8828)	N	N/A										Phase 1
Inflammation - Rheumatoid arthritis	Anti-C5aR-151 (NN8209)	N	N/A										Phase 1
Inflammation - Rheumatoid arthritis	Anti-C5aR-215 (NN8210)	N	N/A										Phase 1
Inflammation - Rheumatoid arthritis	Anti-NKG2A (NN8765)	N	N/A										Phase 2

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- UNITAID
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- Pan American Health Organization
- Drugs for neglected diseases Initiative

- Human Rights Watch
- Treatment Action Campaign (TAC)
- Section 27 (South African public interest law center that incorporates AIDS Law Project)
- Lawyers Collective, India
- Conectas Direitos Humanos
- Justiça Global
- Paz y Esperanza (Peace and Hope)
- Asian Human Rights Commission
- Global Rights (global human rights capacity building organization)
- Calvert Investments
- CalPERS
- Norway's Sovereign Wealth Fund
- Sustainable Asset Management (international investment company with focus on sustainability investments)
- GlaxoSmithKline plc
- Sanofi
- Gilead Sciences
- Merck KGaA
- Roche Holding Ltd.
- Bristol-Myers Squibb Co.
- Abbott Laboratories
- AstraZeneca plc
- Takeda Pharmaceutical Co.

l. Acronyms

AGIs: Actionable Governance Indicators

ATMf: Access to Medicine Foundation

ATMi: Access to Medicine Index

CESCR: Committee on Economic, Social and Cultural Rights

DALY: Disability Adjusted Life Years

EML: Essential Medicines List

HIV / AIDS: Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome

ICESCR: International Covenant on Economic, Social and Cultural Rights

LDC: Least Developed Country

LIC: Lower Income Country

LMIC: Lower Middle Income Country

NCD: Non-Communicable Disease

NTD: Neglected Tropical Diseases

R&D: Research and Development

SME: Small to Medium Sized Enterprises

TB: Tuberculosis

WB: World Bank

WHO: World Health Organization

m. Disclosure of Potential Conflict of Interest

The author of this report holds 18 shares in Johnson & Johnson and 71 shares in Merck, both purchased prior to 2010 and not traded since.

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